

EPA REGISTRATION NUMBER 2517-176
VOLUME 1

PROCESSING REQUEST

Reg # 2517-176

Decision #

Description: New product registration

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated: 3-10-2016

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated: 2/29/2016

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Rita Kumar

Division: RD

Phone: (703) 308-8291

Date: 3-15-2016



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

2517-176

Date of Issuance:

3/10/16

Term of Issuance:

Conditional, Time-Limited
Expires: 3/10/2018

Name of Pesticide Product:

Sergeant's Imidacloprid +
Pyriproxifen Squeeze On for Dogs

Name and Address of Registrant (include ZIP Code):

Kelly R. Hoskins
Sergeant's Pet care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

3/10/16

2. This registration is time-limited and expires 3/10/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
- a. Imidacloprid GDCI-129099-951
 - b. Pyriproxyfen GDCI-129032-1299
 - c. Imidacloprid EDSP-129099
 - d. Pyriproxyfen EDSP-129032

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No. 2517-176."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded

and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 2/29/2016

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291 or via email at kumar.rita@epa.gov.

Enclosure

Sergeant's® Master Label

10 Mar 2016

Version 16.1

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Information in [] is optional.

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FRONT PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and over 7 weeks [old][of age] {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 [-][to] 10 lbs. and 7 weeks [of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and over 7 weeks [old][of age] {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 [-][to] 20 lbs. and 7 weeks [of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and over 7 weeks [old][of age] {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 [-][to] 55 lbs. and 7 weeks [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and over 7 weeks [old][of age] {4.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over][>] 55 lbs. and 7 weeks [of age] or older {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 3 [-][to] 10 lbs. {0.4 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 11 [-][to] 20 lbs. {1.0 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] 21 [-][to] 55 lbs. {2.5 ml size package}

ONLY for dogs [[&][and] puppies]] over 7 weeks [old][of age]] and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

ONLY for dogs [[&][and] puppies]] 7 weeks [of age] or older and [weighing] [more than][over][>] 55 lbs. {4.0 ml size package}

ACCEPTED

Mar 10, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2517-176

1.5cm x 1.5cm on final



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{following text will be in addition to the above required language}

Small Dogs {only for use on label for 3-10 lbs and 7 weeks or older product}

Medium Dogs {only for use on label for 11-20 lbs and 7 weeks or older product}

Large Dogs {only for use on label for 21-55 lbs and 7 weeks or older product}

Extra Large Dogs {only for use on label for >55 lbs and 7 weeks or older product}

ACTIVE INGREDIENTS:

Imidacloprid 9.10%

Pyriproxyfen 0.46%

OTHER INGREDIENTS: 90.44%

[TOTAL] 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][or][Side][Label[s]][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

[ABNs]

[SENTRY® Vet for Dogs Imidacloprid + Pyriproxyfen]

[SENTRY® Advanced for Dogs Imidacloprid + Pyriproxyfen]

[PetArmor® II for Dogs]

[PetArmor® Vet II for Dogs]

[SENTRY® VantaGuard II for Dogs]

[SENTRY® VantaGuard 2 for Dogs]

[SENTRY® VantaGuard 2 Flea Treatment for Dogs]

[SENTRY® VantaGuard 2 Flea Remedy for Dogs]

[SENTRY® Advanced FleaGuard II for Dogs]

[SENTRY® Advanced II for Dogs]

[SENTRY® FleaGuard II for Dogs]

[PetArmor® Advanced II for Dogs]

[PetArmor® Advanced 2 for Dogs]

[PetArmor® Advanced 2 Flea Treatment for Dogs]

[PetArmor® Advanced 2 Flea Remedy for Dogs]

[PetArmor® Advanced 2 Flea Guard for Dogs]

[PetArmor® FleaGuard II for Dogs]

[VantaGuard II for Dogs]

[Advanced FleaGuard II for Dogs]

[Advanced II for Dogs]

[FleaGuard II for Dogs]

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{Begin Optional Active Ingredient Reference Statements}

{Note to Reviewer – the following is an example statement:

Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage® II*

*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® II] [OR]
[Advantage® II is a registered trademark of Bayer Healthcare LLC]}

[[Brand Name] [This product] contains imidacloprid and pyriproxyfen, the active ingredients used in

[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]]*

{Note to reviewer: Text for footnote statement one}

***[Brand Name] [This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of**

[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]]

{Note to reviewer: Text for footnote statement two}

**[Advantage® II] [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]*

is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

[Flea Marketing Claims]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one treatment]

[Prevents further flea infestation for [[four][4] weeks][1 month] with one application]

[One treatment prevents further flea infestation for a month]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for [[four][4] weeks][1 month]]

[Kills fleas within 12 hours on dogs [and prevents further infestations for [up to] [[4][four] weeks][[1][one][a] month]]]

[Kills fleas within 12 hours [of application][on dogs]]

[Kills reinfesting fleas within 2 hours [and protects against further infestation]]

[Kills fleas before eggs can be laid]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.]

[Apply monthly [for effective flea control]]

[Apply monthly [to control and prevent fleas]]

[Monthly treatments are required for optimal control and prevention of fleas]

[Kills fleas]

[Kills fleas even if your dog gets wet]

[Kills fleas within 12 hours, continues to kill for 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis within 12 hours]

[Controls existing flea infestation by killing adult fleas]

[Active against fleas]

[Kills multi-stages of fleas]

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[Kills fleas on dogs]

[Kills fleas on dogs and puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 pounds

[lbs]] {weight range depends upon appropriate ml/fl oz package size}

[(Begins/Starts) working through contact]

[[Brand Name] Offers protection against fleas]

[Once per month topical flea treatment for dogs]

[Monthly topical flea treatment for dogs]

[Once-a-month topical treatment for fleas on dogs]

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs]

[Flea control for puppies and dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Flea control for puppies and dog 7 weeks [of age] or older] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once-a-month topical treatment for fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Prevents and treats flea[s] [infestations]]

[Controls existing infestations by killing adult fleas]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[[Use of Brand Name][Use of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas and may reduce incidence of flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[May be used year-round for control of fleas]

[Controls fleas, which can serve as an intermediate tapeworm host]

[Controls against [irritating] flea bites]

[Prevents further flea infestations on dogs for 30 days [1 month]]

[Prevents flea re-infestations for 30 days [1 month]]

[IGR Marketing Claims]

[Prevents flea eggs from hatching]

[Prevents flea eggs from developing into [biting] adult fleas]

[Prevents the development of flea eggs into [biting] adult fleas]

[Controls existing flea eggs]

[Kills flea eggs]

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[[Brand Name][This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]

[Brand Name] contains [an][the] [insect growth regulator] [IGR] [, Pyriproxyfen] [, in addition to imidacloprid]

[Targets multi-stages of flea lifecycle]

[Controls multi-stages of flea lifecycle]

[Kills multiple flea life stages]

[[Brand Name][This product] is a flea ovicide, larvicide, and adulticide]

[Provides multi-stage flea control]

[Kills [flea eggs and] flea larvae]

[Breaks the flea life cycle]

[Kills flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Prevents multi-stages of the flea life cycle from developing]

[[Brand Name][This product] inhibits the immature flea life stages (except pupae) from developing and preventing them from becoming [biting] adult[s] [fleas]]

[Monthly treatment controls existing flea eggs and fleas and prevents future infestations]

[Controls existing flea eggs and fleas and prevents future infestations for 30 days [1 month]]

[COMBO Marketing Claims]

[3-way flea protection kills adults, larvae and eggs]

[Kills flea eggs, larvae, and [adult] fleas]

[Kills [adult] fleas, flea eggs, and flea larvae]

[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

[All Other Marketing Claims]

[Apply to [dogs and] puppies over 7 weeks old and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[Apply to [dogs and] puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]]
{weight range depends upon appropriate ml/fl oz package size}

[From the makers of PetArmor®]

[[Sergeant's] Caring For Your Pets Since 1868]

[Formulated for Dogs and Puppies Over 7 Weeks [Old][of Age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Formulated for Dogs and Puppies 7 Weeks [of Age] or Older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Dogs and Puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Can be used on puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[The Only Flea Protection You Need For Your Dog[s] When Applied Monthly!]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[Convenient, easy to apply topical solution]

[One Step Hassle Free Protection!]

[Waterproof]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight]

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[and][or] rain]
[Fragrance[-]free]
[Remains effective even after the dog swims]
[Once a month treatment]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[For year-round protection, apply [Brand Name][this product] monthly]
[One tube [vial][pipette]] [1 Month Supply]
[Two tube [vials][pipettes]] [2 Month Supply]
[Three tube [vials][pipettes]] [3 Month Supply]
[Four tube [vials][pipettes]] [4 Month Supply]
[Five tube [vials][pipettes]] [5 Month Supply]
[Six tube [vials][pipettes]] [6 Month Supply]
[9 tube [vials][pipettes]] [9 Month Supply]
[12 tube [vials][pipettes]] [12 Month Supply]
[24 tube [vials][pipettes]] [24 Month Supply]
[Direct to skin [tube][vial][applicator][pipette]]
[Easy to Use] [tube][vial][applicator][pipette]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette][!]]

[Consumer Value Marketing Claims]

[Coupon Inside]
[Save Now!]
[Value Size]
[Club Size]
[Bonus Size]
[Club Pack]
[Great Value]
[Better Value]
[Bonus Pack]
[Bonus Buy]
[[1][2][4][6][7][8][9][X] pack]
[Twin Pack]
[Try Now, Save Later!]
[Z%Free]
[(x) + (x) bonus pack!]
[Buy more and save!]
[Buy X Get Y Free]
[Buy 3 get 1 free]
[(x)% (More) (Free)!]
[33% more free]
[(x) Dose(s) Free!]
[(x) Day(s) (Free)!]
[(x) Month(s) Free!]
[(x) Day(s) of treatment- Free!]
[(x) Tube(s) Free!]
[(x) Applicator(s) Free!]
[(x) Application(s) Free!]

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[33% More Free]

[[New!]] {only for use for 6 months from date of registration}}

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[The active ingredients in [Brand name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [, flea eggs, and flea larvae] on dogs.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][[1][one] month][30 days].]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions:

- **DO NOT ALLOW CHILDREN TO APPLY PRODUCT.**
- Do not use on animals other than dogs.
- Do not allow your dog to ingest this product.
- Do not reapply for [[four] [4] weeks][30 days]
- Use entire contents of tube [vial][applicator][pipette] on each dog. Do not split one tube [vial][applicator][pipette]s between dogs. Do not use multiple tube [vial][applicator][pipette]s on one dog.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right hand side of the back panel}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5 cm x 1.5 cm on final or as indicated]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.



{OUTER PACKAGING}

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution to the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing 3 [-][to] 10 lbs. Do not apply to dogs weighing less than 3 lbs. [including small dogs and puppies, only 7 weeks or older] Apply one

Sergeant's® Master Label

10 Mar 2016

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EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 9 of 13

[tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. Do not apply to dogs weighing less than 11 lbs.

Apply one tube[vial][applicator][pipette] 1.0 mL (0.034 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. Do not apply to dogs weighing less than 21 lbs.

Apply one tube[vial][applicator][pipette] 2.5 mL (0.085 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. Do not apply to dogs weighing less than 55 lbs. Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs. Apply one tube[vial][applicator][pipette] 4.0 mL (0.135 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects [for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours][two hours] and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[[Brand Name {or} This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.] [Apply monthly for flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.]

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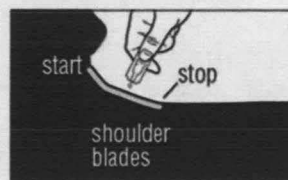
EPA Reg. No. 2517-RTA

Information in [] is optional.

Information in { } is note to reviewer.

Page 10 of 13

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.]



STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F/[25°C])], dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY][PetArmor®] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA With Global Materials]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-RTA
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

Sergeant's® Master Label

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Information in [] is optional.

Information in { } is note to reviewer.

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{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions]

How to Open:

1. Remove product tube[s] [vial[s]][applicator[s]][pipette[s]] from the package.
2. Separate one tube [vial][applicator][pipette] from the others. Hold the tube [vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert tube [vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze tube [vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin as a spot to the dog's back between the shoulder blades. [or] [from the back of the neck to a point midway between the neck and tail.]

Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment {or} application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs[and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth]

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button

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Information in [] is optional.

Information in { } is note to reviewer.

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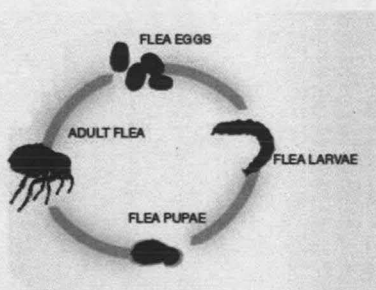
once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	



MADE IN THE USA
WITH GLOBAL MATERIALS



[Flea life cycle diagram] [Flea Life Cycle]

{non-mandatory optional graphics that may be used in addition to the EPA mandatory icon requirements that currently appear on the label.}



*Refund or replacement of product {text footnote to satisfaction guaranteed graphic}

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

Sergeant's® Master Label

10 Mar 2016

Version 16.1

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Information in [] is optional.

Information in { } is note to reviewer.

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TUBE/VIAL LABEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

{Front Label}

{Back Label}

Brand Name {for dogs}

3-10[11-20][21-55][>55] lbs. ≥7 wks

Imidacloprid 9.10%, Pyriproxyfen 0.46%

0.014 fl oz (**or**) 0.034 fl oz (**or**) 0.085 fl oz

(**or**) 0.135 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

CAUTION Read directions and precautions
on package. Use scissors to open.

EPA REG. No. 2517-RTA

{label code}

{EPA REG No may be on either the front or back label}

{Label code refers to Sergeant's product code number assignment to each product}

{END – TUBE/VIAL LABEL}

Kumar, Rita

Resubmission'

From: James Messina <jmessina@exponent.com>
Sent: Thursday, March 10, 2016 4:34 PM
To: Kumar, Rita
Subject: RE: 2517-RTA
Attachments: 2517-RTA Imida + PPF Dog Revised Label 3-10-2016b.docx; 2517-RTA Imida + PPF Dog Revised Label 3-10-2016b clean.docx

I think I go them all. Thank you.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: James Messina
Sent: Thursday, March 10, 2016 2:36 PM
To: 'Kumar, Rita'
Subject: RE: 2517-RTA

Rita,

Please find attached the second updated label per or discussion today.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: James Messina
Sent: Thursday, March 10, 2016 12:00 PM
To: 'Kumar, Rita'
Subject: 2517-RTA

Dear Rita,

Please find attached updated labels for 2517-RTA per our discussion today.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

From: Kumar, Rita
Sent: Thursday, March 03, 2016 2:12 PM
To: 'James Messina'
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); Eagle, Venus
Subject: FW: 2517-rta pre-decisional letter
Attachments: image2016-03-03-132559.pdf

Dear Jim: please see attached pre-decisional letter for the pending dog pour-on, and make the label changes as indicated in the attachment. We would like to have the revised label ASAP.

Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

MAR - 3 2016

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Authorized Agent: James B. Messina
Exponent, Inc.
1150 Connecticut Avenue, NW, Suite 1100, Washington, DC, 20036

Subject: PRIA Predecisional letter – New product registration
Product Name: Sergeant's Imidacloprid + Pyriproxifen Squeeze On for
Dogs
EPA File Symbol: 2517-RTA
Decision Number: 498900

Dear Ms. Hoskins:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the draft label dated March 2, 2015. The necessary label changes are specified on the attached document.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- a. You agree to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- b. You do not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or

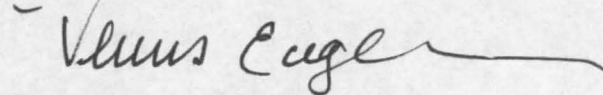
- c. You withdraw the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If you inform EPA that you have concerns as described under (b) above, you will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to you within 2 business days following your written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Rita Kumar at kumar.rita@epa.gov or (703) 308-8291.

Sincerely,

A handwritten signature in black ink that reads "Venus Eagle". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Attachment (1)

Attachment for Predecisional letter for Sergeant's Imidacloprid + Pyriproxifen Squeeze On for Dogs;
2517-RTA

Label Comments for 2517-RTU (Sergeant's Imidacloprid + Pyriproxifen Squeeze On for Dogs)

1. Delete the following claims:
 - Complete flea protection
 - Optimal flea control
 - Optimal flea protection
 - Advanced flea protection
 - Breaks the flea life cycle
 - Controls problems associated with fleas
 - Controls all stages of flea life cycle
 - Controls existing flea eggs and fleas and prevents future infestation (this statement is too broad, must state "controls reinfestation for 30 days")
 - Kills adult fleas before they lay eggs
 - For Dogs (this statement is too broad and unspecific)
 - For use ONLY on dogs –this claim must be qualified with dog's minimum age and weight
 - This product targets all flea life stages
 - Kills [adult] fleas before they lay eggs
 - Apply monthly [for optimal flea control]
 - Apply monthly for optimal flea control and to prevent fleas
 - Stops and prevents further infestation of listed pests for 4 weeks ("stops" and "listed pests" are not acceptable); data is associated with adult fleas
 - Kills all stages of fleas
 - This product is indicated for the treatment and prevention of fleas on dogs ("indicated" is not acceptable)
 - This product is indicated for the treatment and prevention of fleas on dogs over 7 weeks of age and 3 lbs ("indicated" is not acceptable)
 - This product is indicated for the treatment and prevention of fleas on dogs over 7 weeks of age and 3 lbs or greater ("indicated" is not acceptable)
 - Prevents flea infestations (must be specified reinfestation for 1 month)
 - Kills adult fleas before they lay eggs; preventing reinfestation
 - Protects against [irritating] flea bites
 - Any other claim mentioning "all stages of flea life cycle", or "targets all flea life stages" (page 9 and elsewhere)
 - Any reference to the product remaining effective after exposure to sunlight and/or rain (implies enhanced efficacy)
2. All cat icons must be in yellow and black color, and appear in lower right hand corner on the front panel in compliance with 2011 pet spot on mitigation letter sent to all registrants of such products.
3. On page 12, delete the optional graphic for flea life cycle. Flea pupae are not controlled.

4. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a dog in the weight range for the product as packaged;
 - b. The Back Panel: Place the box labeled "Side Effects" at the lower right hand corner of the back panel.
5. The following alternate brand names (ABNs) are duplicate of ABNs for imidacloprid only product – 2517-174:
 - Sentry Vet Advanced Flea for Dogs
 - Sentry Vet FleaGuard for Dogs
 - Sentry Advanced FleaGuard for Dogs
 - Sentry Advanced VetSpot for Dogs
 - PetArmor Advant Flea for Dogs
 - PetArmor FleaGuard Flea for Dogs
 - PetArmor Advanced for Dogs
 - PetArmor Adv Flea for Dogs
 - Armor Adv. Flea for Dogs
 - PetArmor Advet Flea for Dogs

The following ABNs are not acceptable; a qualifier must be provided for 3-Way or 3 Way:

Sentry 3-Way Advanced for Dogs
 PetArmor 3-Way Advanced for Dogs
 Sentry 3 Way Advanced for Dogs
 PetArmor 3Way Advanced for Dogs

Delete all ABNs listed above, and any other that may be duplicates of previously accepted ABNs.

6. On page 3, the paragraph titled "[Begin Optional Active Ingredient Reference Statements]" must be revised to read the same as what we approved for 2517-174 (except for name of this product). Also change the brackets [] to {}.
7. On page 3, change the title Fleas to read as Fleas Marketing Claims. Under this heading, revise the claim "Kills fleas on puppies and dogs" by adding minimum age and weight of dogs.
8. On page 4, the title IGR must be changed to IGR Marketing Claims. Among the claims under this heading delete any with "all stages of the flea life cycle (or lifecycle)" or change to "multi stages.....". Also, delete "Controls existing flea eggs and fleas and prevents future infestations" or add "for 30 days" to this sentence.
9. 8. On page 4, under IGR Marketing Claims, the last statement is a duplicate of one just above it. Delete the duplicate.

10. On page 4 and 5, change the headings "Combo" to "Combo Marketing Claims", and "All Others" to "All Other Marketing Claims". Under the latter heading delete the following claims:
SENTRY
PetArmor
[New][Now][Available without a visit to a veterinarian (this implies product is safer or superior)]. Only New is allowed provided you qualify it with "for 6 months from date of registration".
The claim about remaining effective even after bathing, shampooing.....is repeated.
Delete the duplication
11. On page 6, above Coupon Inside, add the heading "Container Value Marketing Claims".
12. On page 12, under optional graphics, delete the last row with flea pupae from the pictorial table. Also delete the graphic of flea life cycle which has flea pupae in it.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 01, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SERGEANT'S PET CARE PRODUCTS, INC.
10077 SOUTH 134TH STREET
OMAHA, NE 68138-3710

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-FEB-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Receipt for Section 3

S: 981593

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-RTL

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Spot C

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 22-Feb-2016



OPP Rec'd Date: 22-Feb-2016



Front End Date: 22-Feb-2016



Risk Manager Send Date: 23-Feb-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Study

View/Edit



Receipt for Section 3

S: 981592

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-RTA

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeed

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 22-Feb-2016



OPP Rec'd Date: 22-Feb-2016



Front End Date: 23-Feb-2016



Risk Manager Send Date: 23-Feb-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to 75 day deficiency letter

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

TRANSMITTAL DOCUMENT

Date: 02/22/2016

Company:

SERGEANT'S PET CARE PRODUCTS, INC.

10077 SOUTH 134TH STREET

OMAHA, NE 68138-3710

Product Name/EPA Reg. #:

Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA File Symbol 2517-RTA)

Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (EPA File Symbol 2517-RTL)

<u>MRID</u>	<u>Study No.</u>	<u>Study Title</u>
49844801	1	Evaluation of the One Count Dog & Cat Squeeze On White Tube, 0.2ml Fill With No Label as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

2-29-2016. This is a review of acute tox studies (except acute inhalation) that have been cited for registration of 2517-RTA and 2517-RTL. Byron indicated that this can be used for acute toxicity profile of 2517-RTA and 2517-RTL.

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

August 30, 2000

MEMORANDUM

EPA File Symbol: 11556-REX Advantage® Plus 20 for Dogs
DP Barcode: D265777
Case No: 068805
PC Codes: 129099 Imidacloprid; 129032 Pyriproxyfen

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
8/30/2000

To: Helene Daniel/Tina Levine, PM 04
Insecticide-Rodenticide Branch
Registration Division (7505C)

Registrant: Bayer Corp.

ACTION REQUESTED: Review a six-pack of acute toxicity studies. These studies are being used to support the proposed registrations of 6 products, which will be used to control fleas on domestic animals. The MRID numbers of these studies are 45096904 through 45096909.

COMMENTS AND RECOMMENDATIONS: The six acute toxicity studies have all been classified as acceptable, and the proposed product, EPA File Symbol 11556-REL

(ADVANTAGE PLUS 20 FOR DOGS) has the following acute toxicity profile:

Acute Oral LD50	III	Acceptable
Acute Dermal LD50	IV	Acceptable
Acute Inhalation LC50	IV	Acceptable
Primary Eye Irritation	III	Acceptable
Primary Dermal Irritation	IV	Acceptable
Dermal Sensitization	No	Acceptable

These studies were conducted on a formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen. The proposed product has a label declaration of 9.1% Imidacloprid and 0.46% Pyriproxyfen, with 90.44% inert ingredients.

It is emphasized that there are additional studies (companion animal safety studies) which have been submitted in support of the registration of this product. These companion animal safety studies should be reviewed and classified as acceptable before this product is registered.

Since the Oral LD₅₀ value is below 1500 mg/kg, and this product has residential uses, then it will require Child Resistant Packaging (CRP).

The following is the precautionary labeling for this product, based on the acute toxicity profile given above, and as obtained from the Label Review System:

Date: 08/30/00 LABEL REVIEW SYSTEM

ID #: 011556-00125 Advantage Plus 20 for Dogs

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Kumar, Rita

Resubmission:

5982322

2517-RTA

From: James Messina <jmessina@exponent.com>
Sent: Monday, February 29, 2016 6:29 PM
To: Kumar, Rita
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTA EPA Response and 2517-RTL Response
Attachments: Pages from redacted releasable 11556-128 vol.1.pdf; 2517-RTA Form Exemp 2-29-16.pdf; 2517-RTA Basic CSF 2-29-16.pdf; Updated data matrix 2517-RTA 2-29-16 Public.docx; Updated data matrix 2517-RTA 2-29-16.docx; 8570-34 Imid + PPF for Dogs.pdf; Compare 3-2-15 and 2-8-16 labels - Word Versions.docx

Dear Rita,

Thank you for your email. I was hoping to speak with you today before I replied but we did not connect. I hope we can discuss the responses tomorrow morning. I am available most of the day, so please let me know when is convenient for you.

Based upon our review of your email, we have revised the following documents for each product:

1. CSF [REDACTED] as sources of pyriproxyfen on the Basic, updated date, no other changes)
2. Updated formulators exemption form (same as above)
3. Data matrix (we placed the companion animal generic data under Pyriproxyfen Generic Data for Companion Animal Use, updated dates)
4. Updated 8570-34 (updated date)

#1 Acute Oral Toxicity

You note below that both products will be listed as EPA Toxicity Category II. We checked the Bayer Animal Health registrations as we are citing their acute oral toxicity study as well as our own. The BAH registrations (11556-125, 11556-127, 11556-128, 11556-130, 11556-150, 11556-151 and 11556-152) all categorize the products as EPA Toxicity Category III. Attached is a copy of the EPA DER for the BAH study Sergeant's cited listing it as an EPA Toxicity Category III. We also checked the Label Review Manual and it states:

Acute Oral Toxicity

Category II: LD50 of 50 – 500 mg/kg

Category III: LD50 of 500 – 5000 mg/kg

The BAH acute oral data and Sergeant's acute oral data place the LD50 between 1000 – 1500 mg/kg, which is within the EPA Toxicity Category III.

The CRP requirement is based on an acute oral LD50 < 1500 mg/kg.

Based upon the above, the correct EPA Toxicity Category for Sergeant's products is III. The pending draft labels reflect the appropriate language.

#2 CRP

Thank you for reviewing the CRP certification statements. We hope that the Agency does not have to formally review the actual study as it is confirmatory of the existing CRP data (12 studies) and it is 100% passing.

#3 CSFs

The revised CSFs are attached.

#4 Generic Data Requirements for Pyriproxyfen

We cited two additional generic studies to support the use of pyriproxyfen in the data matrix sent to EPA on February 22 and in the attached versions. Based upon publically available information, we know we have cited more pyriproxyfen generic data than Hartz Mountain, Promika and Bayer Animal Health and that we cited the same two generic pyriproxyfen studies as another registrant that EPA approved earlier in February 2016. We do not know of any current registrants that cited residue transfer (petting) data on pyriproxyfen to support the same or substantially similar registrations. We did update the data matrix to list the two citations under a heading "Pyriproxyfen Generic Data for Companion Animal Use".

EPA specifically noted we did not cite a residue transfer (petting) study for pyriproxyfen. Based upon our review of data matrices available via FOIA, no other current registrants cited a residue transfer study for pyriproxyfen. We also searched NPIRS and did not locate a residue transfer study for pyriproxyfen. Further, based upon previous EPA reviews of pyriproxyfen, default SOP values have been used for evaluation of pyriproxyfen in EPA's risk assessments for pet uses.

Based on the above, our data matrix sufficiently addresses the generic companion animal data requirements for pyriproxyfen.

Labels

We have attached labels in track changes version for you. Please note, that we compared the most recent label to labels provided to EPA in March 2015. There are many differences based upon the recent imidacloprid only approvals.

Please let me know if you have any questions. I will send the files for 2517-RTL in a following email.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent, Inc.
Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC 20036
O: 202.772.4932
M: 301.908.1181
jmessina@exponent.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Friday, February 26, 2016 4:45 PM
To: James Messina
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: RE: 2517-RTA EPA Response and 2517-RTL Response
Importance: High

Dear Jim: Thanks for the response for both cat and dog products. My comments below apply to both products:

1. The newly cited acute toxicity study is acceptable to satisfy the acute toxicity data requirement, and this product will be placed in toxicity category II for this exposure route.
2. We will review the CRP certification and study, and let you know if there are any issues with it.

3. The revised basic CSF dated 1/25/2016 is not acceptable. Two of the alternate sources of pyriproxyfen (PPF) [REDACTED], and are not acceptable. The other ingredients in these two products are likely to change the toxicity profile of the basic formulation. Please delete these two sources and revised the Formulator's Exemption form accordingly.
4. The data matrix dated February 4, 2016 does not adequately address the generic data requirements for pyriproxyfen. It does not cite a residue transfer (petting) study that further refines the safety finding for companion animal use. Also, you need to place the citations for companion animal use under this specific heading, and not combine these with efficacy citations.

Please address these issues ASAP, and also provide a highlighted copy of revised labeling dated 2/8/2016.

Regards,

Rita

From: James Messina [mailto:jmessina@exponent.com]

Sent: Monday, February 22, 2016 12:17 PM

To: Kumar, Rita <Kumar.Rita@epa.gov>

Cc: Eagle, Venus <Eagle.Venus@epa.gov>; Carrie Daniels <cdaniels@exponent.com>; Kelly Hoskins (Kelly.Hoskins@perrigo.com) <Kelly.Hoskins@perrigo.com>

Subject: 2517-RTA EPA Response

Dear Rita,

Please find attached a PDF of Sergeant's Pet Care Products, Inc. (Sergeant's) response to EPA's deficiency letter dated 2/16/2016. The following is a summary of the response:

- Addressed acute oral toxicity: rely upon 49510307 and 45096904
- Package product in CRP: submitting one CRP study (0.2 ml fill volume) with 100% passing for adults and children plus citing 12 previously accepted by EPA Sergeant's CRP studies. This support packaging in CRP
- CRP self-certification statement
- Updated data matrix to address pyriproxyfen generic data for companion animal
- Limited imidacloprid source to a TGA1 labelled specifically for companion animal

As noted, the one new CRP study resulted in 100% passing (adults and children) and this study just covers the lower fill volume range to allow this product to be packaged in CRP. Based on the fact that the new study is confirmatory to the existing CRP data, it resulted in 100% passing and we are self-certifying, we request that EPA not require that the new study be reviewed prior to issuing the registration.

Please review the information in this email and let me know if you have any questions. I am forwarding the original to document processing today. I will also call you to discuss our submission in more detail.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

August 30, 2000

MEMORANDUM

EPA File Symbol: 11556-REI Advantage® Plus 10 for Dogs

DP Barcode: D265773

Case No: 068809

PC Codes: 129099 Imidacloprid; 129032 Pyriproxyfen

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
8/30/2000

To: Helene Daniel/Tina Levine, PM 04
Insecticide-Rodenticide Branch
Registration Division (7505C)

Registrant: Bayer Corp.

ACTION REQUESTED: Review a six-pack of acute toxicity studies. These studies are being used to support the proposed registrations of 6 products, which will be used to control fleas on domestic animals. The MRID numbers of these studies are 45096904 through 45096909.

COMMENTS AND RECOMMENDATIONS: The six acute toxicity studies have all been classified as acceptable, and the proposed product, EPA File Symbol 11556-REI

(ADVANTAGE PLUS 10 FOR DOGS) has the following acute toxicity profile:

Acute Oral LD50	III	Acceptable
Acute Dermal LD50	IV	Acceptable
Acute Inhalation LC50	IV	Acceptable
Primary Eye Irritation	III	Acceptable
Primary Dermal Irritation	IV	Acceptable
Dermal Sensitization	No	Acceptable

These studies were conducted on a formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen. The proposed product has a label declaration of 9.1% Imidacloprid and 0.46% Pyriproxyfen, with 90.44% inert ingredients.

It is emphasized that there are additional studies (companion animal safety studies) which have been submitted in support of the registration of this product. These companion animal safety studies should be reviewed and classified as acceptable before this product is registered.

Since the Oral LD₅₀ value is below 1500 mg/kg, and this product has residential uses, then it will require Child Resistant Packaging (CRP).

The following is the precautionary labeling for this product, based on the acute toxicity profile given above, and as obtained from the Label Review System:

Date: 08/30/00 LABEL REVIEW SYSTEM

ID #: 011556-00128 Advantage Plus 10 for Dogs

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN:

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100, formerly §81-1))

Product Manager: 04
MRID No.: 45096904

Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: September 30, 1999
Study No.: 99-A12-DZ

Testing Facility: Bayer Corporation, Agriculture Division Toxicology, Stilwell, Kansas
Author: Sturdivant, D.W.

Quality Assurance (40 CFR §160.12): Included (p. 6-7)

Test Material: Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On; a clear yellow to light brown liquid, Lot No. 99-625-41

Species: Rat; Wistar Hannover (Cr:Wi(Glx/BRL/Han)IGS BR
Age: Young adult (Males: 9-10 weeks; Females: approximately 12 weeks)
Weight: Males: 194-242 g; Females: 159-207 g
Source: Charles River Laboratories, Raleigh, NC

Conclusion:

1. **LD₅₀ (mg/kg):**
 Males: = 1283 (95% C.L: 680-1678) mg/kg
 Females: = 1000 (95% C.L: not calculable) mg/kg
 Combined: = not reported
2. **The estimated LD₅₀ is** = 1000 mg/kg
3. **Tox. Category: III** **Classification: Acceptable**

Procedure (including deviations from 870.1100): "Groups of six male and six female rats were treated by gavage at varying concentrations of Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On in vehicle (deionized water/PEG 200 1:1 v/v)." Groups of male rats were treated at nominal doses of 1000, 1500 and 2000 mg/kg while groups of female rats were treated at nominal doses of 500, 1000 and 2000 mg/kg... "Six male and six female rats were dosed with vehicle and served as concurrent control groups."

Results:

Dosage (mg/kg)*	Number of Deaths/Number Tested		
	Males	Females	Combined
0	0/6	0/6	0/12
500	-	0/6	-
1000	1/6	3/6	4/12
1500	5/6	-	-
2000	5/6	6/6	11/12

*Average actual doses were 0, 1038, 1542 and 2145 mg/kg for males and 0, 614, 1027 and 2071 mg/kg for females.

Observations: There were no clinical signs of toxicity in the females dosed at 500 mg/kg. Symptoms at 1000 mg/kg included: brown nasal staining, brown oral staining, decreased activity, tremors and (females only) urine staining. Symptoms at 1500 and 2000 mg/kg included ataxia, decreased activity and tremors. Mortalities, when they occurred, were on days 0 to 2.

Gross Necropsy: "The following compound-related gross observations were observed at necropsy only in animals that were found dead: salivation and nasal discharge in males and females, red discolored lungs and urine in males. There were no gross observations noted in females from the 500 mg/kg dose group or in males from the 1000 mg/kg dose group. Also, there were no gross observations noted in any surviving, treated male or female rats or in control male or female rats.



United States
Environmental Protection Agency
 Washington, DC 20460

Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Sergeant's Pet Care Products, Inc.
 10077 South 134th Street
 Omaha, NE 68138-3710

EPA File Symbol/Registration Number
 2517-RTA

Product Name
 Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

Date of Confidential Statement of Formula (EPA Form 8570-4)
 February 29, 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid, Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

Active Ingredient	Product Name	Registration Number
Imidacloprid		
Pyriproxyfen		
Pyriproxyfen		
Pyriproxyfen		
Pyriproxyfen		
Signature 	Name and Title Kelly R. Hoskins Manager of Regulatory Affairs	Date February 29, 2016

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
 Yellow - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-RTA
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 2/29/2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelly R. Hoskins</i>	Date 2/29/2016	Typed or Printed Name and Title Kelly R. Hoskins, Director of Regulatory Affairs
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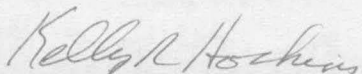


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date: February 29, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 1 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307	Sergeant's Pet Care Products	OWN	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096904	Bayer Animal Health	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096905	Bayer Animal Health	PAY	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306	Sergeant's Pet Care Products	OWN	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/29/2016	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: February 29, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 2 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096907	Bayer Animal Health	PAY	
870.2500	Primary Dermal Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096908	Bayer Animal Health	PAY	
870.2600	Dermal Sensitization Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096909	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Seven Week Old Puppies	45097101	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Adult Dogs	45097102	Bayer Animal Health	PAY	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORTJAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer Animal Health	OLD	
Pyriproxyfen Generic Data for Companion Animal Use					
NA	Evaluation of the Toxicology and Potential Health Risks Associated with Indoor, Nonfood Uses of Sumilarv; Unpublished study prepared by Technology Services Group, Inc. 71 p.	42182701	McLaughlin Gormley King Company	OLD	
870.3200	S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Unpublished study prepared by Life Science Research Ltd. 320 p.	42178309	McLaughlin Gormley King Company	OLD	
Signature <i>Kelly R. Hoskins</i>		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/29/2016	

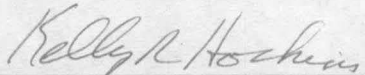
→ Imidacloprid generic data citations are not included here because the source product for imi is registered for use on companion animals, and is entitled to formulator's exemption.⁵¹



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

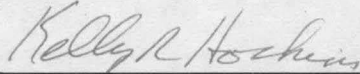
Date: February 29, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 3 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs	43679609	Bayer Animal Health	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs	43679610	Bayer Animal Health	OLD	
810.3300	A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Animal Health	PAY	
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report)	44256901	Bayer Animal Health	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs	44256902	Bayer Animal Health	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs	44256903	Bayer Animal Health	OLD	
810.3300	Nylar 50 (percent) Concentrate: Product Performance/Efficacy Reports. Unpublished study prepared by McLaughlin Gormley King. 79 p.	45086801	McLaughlin Gormley King Company	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/29/2016	



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DATA MATRIX

Date: February 29, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 4 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67 ml White Applicator with Orange Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614202	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34 ml White Applicator with Green Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614203	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68 ml White Applicator with Red Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614204	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02 ml White Applicator with Blue Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614205	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67ml White Applicator with Orange Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059803	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34ml White Applicator with Green Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059804	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68ml White Applicator with Red Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059805	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02ml White Applicator with Blue Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059806	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Use of One Tube 1x Child Resistant Unit Packaging Data (Child and Senior) to Support All Unit Configurations for Fipronil Based Spot-On Registrations	48614201	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48650101	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Amended Report: Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48279601	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (1x), scissors to open - F=1 as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48613701	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the One Count Dog & Cat Squeeze On White Tube, 0.2 ml fill with no label as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.		Sergeant's Pet Care Products, Inc.	OWN	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/29/2016	

Kumar, Rita

Resubmission:
S 982320

From: James Messina <jmessina@exponent.com>
Sent: Monday, February 22, 2016 12:17 PM
To: Kumar, Rita
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: 2517-RTA EPA Response
Attachments: 2517-RTA EPA Response 2-22-2016.pdf

Dear Rita,

Please find attached a PDF of Sergeant's Pet Care Products, Inc. (Sergeant's) response to EPA's deficiency letter dated 2/16/2016. The following is a summary of the response:

- Addressed acute oral toxicity: rely upon 49510307 and 45096904
- Package product in CRP: submitting one CRP study (0.2 ml fill volume) with 100% passing for adults and children plus citing 12 previously accepted by EPA Sergeant's CRP studies. This support packaging in CRP
- CRP self-certification statement
- Updated data matrix to address pyriproxyfen generic data for companion animal
- Limited imidacloprid source to a TGA1 labelled specifically for companion animal

As noted, the one new CRP study resulted in 100% passing (adults and children) and this study just covers the lower fill volume range to allow this product to be packaged in CRP. Based on the fact that the new study is confirmatory to the existing CRP data, it resulted in 100% passing and we are self-certifying, we request that EPA not require that the new study be reviewed prior to issuing the registration.

Please review the information in this email and let me know if you have any questions. I am forwarding the original to document processing today. I will also call you to discuss our submission in more detail.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Monday, February 22, 2016 12:18 PM
To: Kumar, Rita
Cc: Eagle, Venus; Carrie Daniels; Kelly Hoskins (Kelly.Hoskins@perrigo.com)
Subject: 2517-RTL EPA Response
Attachments: 2517-RTL EPA Response 2-22-2016.pdf

Dear Rita,

Attached is the response specific to 2517-RTL. The same information from the previous email pertains to this submission.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

February 22, 2016

Rita Kumar
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs
EPA File Symbol 2517-RTA

Dear Ms. Kumar:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995):

- Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs
EPA File Symbol 2517-RTA

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting this child resistant packaging certification to support the new end-use product for Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs. This certification statement is based on data submitted to the Agency under the following MRID numbers: 48059803, 48059804, 48059805, 48059806, 48614201, 48614202, 48614203, 48614204, 48614205, 48650101, 48613701, 48059503, 48279601, and a new study being submitted as part of this package.

The submission covers CRP packages (tubes) with fill volumes in the range of 0.2 – 4.02 ml. The product noted above is packaged in fill volumes of 0.4, 1.0, 2.5 and 4.0 mL. The how to open instruction in the Agency accepted MRID Number 48650101 is "**How to open:** Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line."

If you have any questions, please contact me at 402-938-7079 or kelly.hoskins@perrigo.com.

Sincerely,

Kelly R. Hoskins
Director of Regulatory Affairs



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

February 22, 2016

Maggie Rudick
c/o Rita Kumar
Registration Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Support
Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs
EPA File Symbol 2517-RTA
Sergeant's Imidacloprid + Pyriproxyfen Spot-On for Cats
EPA File Symbol 2517-RTL

Dear Ms. Rudick:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting information on its available Child Resistant Packaging (CRP) studies to support the following pending registration applications:

- Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs (EPA File Symbol 2517-RTA)
- Sergeant's Imidacloprid + Pyriproxyfen Spot-On for Cats (EPA File Symbol 2517-RTL)

CRP data are required for both new products because the EPA determined that the acute oral LD₅₀ value could not be established at >1500 mg/kg based upon the submitted data.

Sergeant's met with EPA staff on multiple occasions to discuss CRP packaging. The most recent meeting with EPA on CRP was on April 28, 2015 and included Kable Davis, Maggie Rudick, Lindsay Rowe and Bonaventure Akinlosotu. During this meeting we confirmed with EPA that if Sergeant's conducted CRP data that were acceptable and that covered the fill volumes, the Agency would rely upon this data to support product registrations.

During the meeting we also confirmed with EPA that conducting the one new study on the 0.2 ml single container (1x) represented the worst-case scenario.

The new CRP study (0.2 ml, 1x) resulted in a Child-Resistant Effectiveness of 100% and a Senior-Use Effectiveness (SUE) of 100%. There were no failures of the Sergeant's packaging with 0.2 ml fill volume.

M. Rudick

Twelve of the thirteen CRP studies listed below were submitted to the Agency in support of various Sergeant's dog/cat squeeze-on product registrations, including those which were registered under EPA Registration Numbers: 2517-134, -136, -140, -141, -142, -143, -149, -150, and -151. The one new CRP study being submitted with this letter covers the lowest possible fill volume of 0.2 ml. Therefore, the available CRP data covers the Sergeant's CRP packaging in fill volumes ranging from 0.2 – 4.02 ml.

The following table lists the supporting CRP studies by MRID number. All CRP data except the one new study have been reviewed and accepted by EPA.

MRID Number	Fill Weight (ml)	Configuration	EPA Status	Child Pass Rate	SUE Pass Rate
NEW	0.2	1x		100%	100%
48650101	Revised "How to Open" Instructions (0.50 ml, 3x)	NA	Acc.	100%	100%
48279601	0.5	3x	Acc.	100%	90%
48613701	0.5	1x	Acc.	98%	99%
48059803	0.67	3x	Acc.	100%	98%
48614202	0.67	1x	Acc.	96%	100%
48059804	1.34	3x	Acc.	100%	95%
48614203	1.34	1x	Acc.	98%	100%
48059805	2.68	3x	Acc.	96%	98%
48614204	2.68	1x	Acc.	100%	100%
48059806	4.02	3x	Acc.	98%	97%
48614205	4.02	1x	Acc.	98%	100%
48614201	Support Document for Multiple Package Configurations	NA	Acc.	NA	NA

The fill volumes for the two pending registrations are as follows:

- Sergeant's Imidacloprid + Pyriproxyfen Squeeze-On for Dogs (EPA File Symbol 2517-RTA): 0.4, 1.0, 2.5, and 4.0 ml
- Sergeant's Imidacloprid + Pyriproxyfen Spot-On for Cats (EPA File Symbol 2517-RTL): 0.23, 0.4, and 0.8 ml

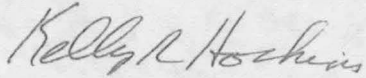
The pending fill volumes fall within the current CRP data range of 0.2 – 4.02 ml.

Based upon the existing and new CRP data, Sergeant's requests that EPA approve the two pending product registration applications without the need to review the new CRP study. All CRP data submitted and/or cited by Sergeant's results in high passing values for children and adults. Additionally, the new CRP study resulted in 100% passing (children and adults).

M. Rudick
February 22, 2016
Page 3 of 3

If you have any questions, please contact me at 402-938-7079 or kelly.hoskins@perrigo.com.

Sincerely,

A handwritten signature in cursive script that reads "Kelly R. Hoskins".

Kelly R. Hoskins
Director of Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-RTA
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 2/22/2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Kelly R. Hoskins

Date

2/22/2016

Typed or Printed Name and Title

Kelly R. Hoskins, Director of Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-RTA
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 2/22/2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

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SECTION I: METHOD OF DATA SUPPORT (Check one method only)

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--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Kelly R. Hoskins

Date

2/22/2016

Typed or Printed Name and Title

Kelly R. Hoskins, Director of Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date: February 22, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 1 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307	Sergeant's Pet Care Products	OWN	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096904 <i>new citation *</i>	Bayer Animal Health	OLD	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096905	Bayer Animal Health	PAY	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306	Sergeant's Pet Care Products	OWN	
Signature <i>Kelly R. Hoskins</i>		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/22/2016	

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*This was referred in Byron's review



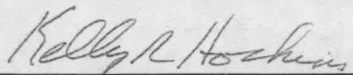
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DATA MATRIX

Date: February 22, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 2 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096907	Bayer Animal Health	PAY	
870.2500	Primary Dermal Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096908	Bayer Animal Health	PAY	
870.2600	Dermal Sensitization Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096909	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species. Seven Week Old Puppies	45097101	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species. Adult Dogs	45097102	Bayer Animal Health	PAY	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer Animal Health	OLD	
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs	43679609	Bayer Animal Health	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs	43679610	Bayer Animal Health	OLD	
810.3300	A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Animal Health	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/22/2016	

Working



Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date: February 22, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 3 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300 <i>efficacy</i>	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report)	44256901	Bayer Animal Health	OLD	
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs	44256902	Bayer Animal Health	OLD	
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs	44256903	Bayer Animal Health	OLD	
810.3300	Nylar 50 (percent) Concentrate: Product Performance/Efficacy Reports. Unpublished study prepared by McLaughlin Gormley King. 79 p.	45086801	McLaughlin Gormley King Company	PAY	
NA	Evaluation of the Toxicology and Potential Health Risks Associated with Indoor, Nonfood Uses of Sumilarv; Unpublished study prepared by Technology Services Group, Inc. 71 p.	42182701	McLaughlin Gormley King Company	OLD	
870.3200	S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Unpublished study prepared by Life Science Research Ltd. 320 p.	42178309	McLaughlin Gormley King Company	OLD	
Signature <i>Kelly R. Hoskins</i>		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/22/2016	

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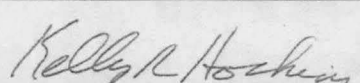
*These need to be placed under the heading
PPF Generic Data for Comp. Animal Use.*



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DATA MATRIX

Date: February 22, 2016		EPA Reg No./File Symbol: 2517-RTA		Page 4 of 4	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67 ml White Applicator with Orange Label Indicator (1x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614202	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34 ml White Applicator with Green Label Indicator (1x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614203	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68 ml White Applicator with Red Label Indicator (1x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614204	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02 ml White Applicator with Blue Label Indicator (1x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48614205	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 0.67ml White Applicator with Orange Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059803	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 1.34ml White Applicator with Green Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059804	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 2.68ml White Applicator with Red Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059805	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Dog Squeeze On 4.02ml White Applicator with Blue Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48059806	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Use of One Tube 1x Child Resistant Unit Packaging Data (Child and Senior) to Support All Unit Configurations for Fipronil Based Spot-On Registrations	48614201	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48650101	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Amended Report: Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (3x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48279601	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the Cat Squeeze On 0.5ml White Applicator with Purple Label Indicator (1x), scissors to open - F=I as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.	48613701	Sergeant's Pet Care Products, Inc.	OWN	
40 CFR Part 157.32	Evaluation of the One Count Dog & Cat Squeeze On White Tube, 0.2 ml fill with no label as a Poison Prevention Package for Sergeant's Pet Care Products, Inc.		Sergeant's Pet Care Products, Inc.	OWN	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 2/22/2016	

Kumar, Rita

From: Kumar, Rita
Sent: Tuesday, February 16, 2016 4:56 PM
To: 'James Messina'
Cc: Eagle, Venus
Subject: FW: 2517-RTL and -RTA second 75-day letter.
Attachments: image2016-02-16-165736.pdf

Importance: High

Dear Jim: Please see attached second 75-day letter regarding these two applications.
Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

FEB 16 2016

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

OPP Decision Number: D-498900; D-498686

Registrant Name: Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.

Registrant Address 10077 South 134th Street
Omaha, NE 68138-3710

Authorized Agent: James B. Messina
Exponent, Inc.
1150 Connecticut Avenue, NW, Suite 1100, Washington, DC, 20036

Subject: Data Deficiency

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats

EPA File Symbol: 2517-RTA; 2517-RTL

Application Date: 12/23/2014

EPA Receipt Date: 12/24/2014

PRIA Date: 3/10/16

Dear Ms. Hoskins:

The Agency has reviewed the information submitted by you to address the deficiencies identified in Agency's letters dated 10/22/2016 for the subject applications and has determined that the deficiencies are not addressed with this additional information. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

In accordance with 40 CFR 152.105, EPA will allow another 75 days from the date of this letter ending May 2, 2016 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond

to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The acute oral toxicity study in MRID 49510307 remains classified as supplementary. In your submission you stated that "Based on the two similar Hartz products (MRID 49287704 and 49287804), with the same exact active ingredient percentages of imidacloprid (9.1%) and pyriproxyfen (0.46%), the range of oral LD50 values span from 2311 mg/kg to 1650 mg/kg. This range is different from the Bayer product that has a higher pyriproxyfen percentage (0.9%) and a subsequently lower LD50 value of 1283 mg/kg (males) and 1000 mg/kg (females). In this comparison, the lower acute oral LD50 values and perhaps more acutely toxic Bayer product may be due to the higher percentage of pyriproxyfen and/or variation in formulation specifications in the product. Using this rationale, the Sergeant's product is more similar to the Hartz products and therefore, those LD50 values (1650 mg/kg and 2311 mg/kg) form the basis for the preliminary starting dose for the acute oral LD50 for Sergeant's product...". We have examined and compared the CSFs for 2517-RTA and 2517-RTL with the two Hartz products, and the Bayer product. Based on comparisons of the full formulas for these products, EPA has determined that the data for these other products cannot be used to support your application to register 2517-RTA and 2517-RTL. We have concerns regarding the inerts in the formulation of these two products.

A new acute toxicity study is needed to define the acute toxicity profile for this product.

2. As indicated above, we are not able to establish an acute oral toxicity of >1500 mg/kg from submitted data. Therefore child-resistant packaging certification would be needed unless a new acute toxicity study demonstrates that the product has an acute oral toxicity LD50 greater than 1.5 g/kg.
3. As indicated to you before in our letter dated 10/22/2015, the source products in the basic and alternate Confidential Statements of Formula (CSFs) are not registered for companion animal use; therefore you must satisfy the generic data requirements for this use. Generic data were used to make the safety finding for companion animal use, when this use was first registered. If you are unable to identify the data, then a generic cite-all with an offer to pay could be used to address this deficiency.

If you want to pick the Cite-All option to satisfy the generic data requirements, then you must submit a generic data matrix for companion animals, and list all companies that have submitted data for this use. Further a revised Certification with Respect to Citation of Data Form would need to be submitted with Cite-All option checked in the General Offer To Pay box.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

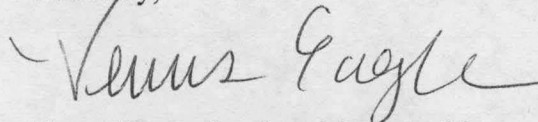
FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on March 10, 2016. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than March 1, 2016 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than March 1, 2016, 2015 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by March 1, 2016, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by March 1, 2016 by e-mail to kumar.rita@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

James Messina

Resubmission:

From: James Messina
Sent: Monday, February 08, 2016 6:34 PM
To: 'Kumar, Rita'; eagle.venus@epa.gov
Cc: Carrie Daniels
Subject: 2517-RTA and 2517-RTL
Attachments: 2517-RTA Imida + PPF Dog Revised Label 2-8-2016.docx; 2517-RTL Imida + PPF Cat Revised Label 2-8-2016.docx

S 982328 - RTL

S 982318 - RTA

Importance: High

Dear Rita and Venus,

Please find attached updated product labels for 2517-RTA and 2517-RTL for your review. The updated labels incorporate EPA's relevant comments from the two products you registered last week. These labels should simplify the EPA review process.

We also need to have EPA provide copies of the acute toxicity review for our November 2015 response. My understanding is that this is complete. If so, can you please email us a copy of the review this week?

We also need to discuss the TGA for pyriproxyfen. Please refer to my emails dated 2/1/2016 and 1/25/2016.

I will call Rita tomorrow to discuss the above. We want to work with EPA to obtain the two registrations as soon as possible. We appreciate all of the Agency's efforts on these actions.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

From: Kumar, Rita
Sent: Monday, February 08, 2016 2:08 PM
To: Knorr, Michele
Cc: Eagle, Venus
Subject: FW: A question about two cat and dog spot-on applications

Importance: High

Michele: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thanks,
Rita

From: Kumar, Rita
Sent: Monday, February 08, 2016 12:47 PM
To: Knorr, Michele <Knorr.Michele@epa.gov>
Subject: FW: A question about two cat and dog spot-on applications
Importance: High

Hi Michelle: [REDACTED]

Thanks,
Rita

From: Kumar, Rita
Sent: Monday, February 08, 2016 12:42 PM
To: Koch, Erin <Koch.Erin@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: A question about two cat and dog spot-on applications
Importance: High

Hi Erin: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thanks,
Rita

James Messina

From: James Messina
Sent: Sunday, January 24, 2016 12:23 PM
To: 'Kumar, Rita'; eagle.venus@epa.gov
Cc: Carrie Daniels
Subject: 2517-RTA and 2517-RTL Pyriproxyfen Support
Attachments: Sergeant PPF.pdf; indoor-nonfood.pdf; 2517-RTL Form Exemp 1-25-16.pdf; 2517-RTL Basic CSF 1-25-16.pdf; 2517-RTA Form Exemp 1-25-16.pdf; 2517-RTA Basic CSF 1-25-16.pdf

Categories: Red Category

Dear Rita and Venus,

Please find attached the following in support of the pending applications for 2517-RTA and 2517-RTL:

1. A document responding to EPA's indication that none of the EPA registered sources (TGA/MUP) for pyriproxyfen cited by Sergeant's are approved for formulation of companion animal end-use products
2. Updated CSFs and formulators' exemption forms for both pending applications limiting the imidacloprid
[REDACTED]

We request that EPA review the attached information on pyriproxyfen and then schedule a meeting or a call with us for early next week. We want to work with EPA to resolve the pyriproxyfen issue it has raised right away. This will enable us to provide you with CSFs (if needed) well in advance of the current PRIA due date of March 19, 2016.

Additionally, can you please provide an update on EPA's review of our response letters dated November 17, 2015? Lastly, we will plan to update the labels for these pending products once we receive the stamped approved labels for the imidacloprid only products (2517-RTU and 22517-RTG). Our plan is to use them as a general guide.

We look forward to speaking with both of you next week. Thanks in advance for your time.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
E^xponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

January 19, 2016

MEMORANDUM:

Subject: Name of Pesticide Product: SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN
SQUEEZE ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTA
DP Barcode: DP 430641
Decision No.: 498900
Submission #: 978464
Action Code: R315
PC Codes: 129099 (Imidacloprid: 9.10%)
129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist *Byron T. Backus*
CITAB *Jan-19-2016*
Registration Division (7505P)

Through: John Redden, M.S., Senior Risk Assessor *JCR*
CITAB
Registration Division (7505P)

To: Rita Kumar RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
<u>Other Ingredients:</u>	<u>90.44%</u>
TOTAL	100.00%

ACTION REQUESTED: "...Please see this response by the registrant to your acute toxicity review of 2517-RTA and -RTL. An electronic copy of this was sent to you two weeks ago. Registrant has submitted additional information to upgrade the acute oral study that you classified as unacceptable in

your review dated 9/18/2015. The same information will apply to your review for 2517-RTL, dated Oct. 6, 2015, because the two products (2517-RTA and -RTL) are identical in formulation, and the same acute oral toxicity study was submitted to support these two registrations. Registrant has also cited two additional acute oral toxicity studies to support this rebuttal, and copies of revised data matrix for both products are enclosed...”

COMMENTS AND RECOMMENDATIONS:

1. The registrant's comments in their response includes the following: “The acute oral toxicity study, MRID 49510307, was designed based on all publicly available toxicological information on substantially similar products, which demonstrate the oral LD₅₀ values for substantially similar formulated products are \geq 1650 mg/kg...”
2. It is also stated (p. 4 of the response) that: “Based on the two similar Hartz products (MRID 49287704 and 49287804), with the same exact active ingredient percentages of imidacloprid (9.1%) and pyriproxyfen (0.46%), the range of oral LD₅₀ values span from 2311 mg/kg to 1650 mg/kg. This range is different from the Bayer product that has a higher pyriproxyfen percentage (0.9%) and a subsequently lower LD₅₀ value of 1283 mg/kg (males) and 1000 mg/kg (females). In this comparison, the lower acute oral LD₅₀ values and perhaps more acutely toxic Bayer product may be due to the higher percentage of pyriproxyfen and/or variation in formulation specifications in the product. Using this rationale, the Sergeant's product is more similar to the Hartz products and therefore, those LD₅₀ values (1650 mg/kg and 2311 mg/kg) form the basis for the preliminary starting dose for the acute oral LD₅₀ for Sergeant's product...”
3. This reviewer has examined and compared the CSFs for 2517-RTA, 2596-181, 2596-182, and 11556-128 (there is no current registration under 11556-126). It is concluded that one of the inerts in the formulation for 2517-RTA has potential toxicity; this inert is either present at a considerably lower percentage or is absent from 2596-181 and/or 2596-182. On this basis, we cannot accept the argument that the Sergeant's product is “more” similar to the Hartz products, or that data can be combined from MRIDs 49510307 (2517-RTA), 49287704 (2596-181) and 49287804 (2596-182) to generate an LD₅₀ value of 1711.89 mg/kg which would be applicable to 2517-RTA and 2517-RTL.
4. The registrant has also suggested that the lower acute oral LD₅₀ values of the Bayer product may involve a higher percentage of pyriproxyfen. Pyriproxyfen has a very low toxicity to mammalian species; an oral LD₅₀ rat study (MRID 41321711) with technical (97.2%) pyriproxyfen administered in corn oil resulted in no deaths at the highest dose level administered (5000 mg/kg). Since 2517-RTA and 2517-RTL and the other products all contain less than 1% pyriproxyfen, it is concluded that there would be no significant differences in oral toxicity between these products that would be related to slight percentage variations involving this active ingredient.
5. The position that the oral LD₅₀ study in MRID 49510307 cannot be used to establish an LD₅₀ value less than 1500 mg/kg remains unchanged.

no
BTB
2/2/16

Recommendation of Division Directors			
Negotiated Due Dates			
Decision #:498686	Registration #:2517-RTL	Petition #:	
498900	2517-RTA		
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Imidacloprid and pyriproxifen			
Fee Category: R315		PRIA Decision Time Frame: 9 months	
Submitted by: Rita		Kumar	Branch: OCSP/OPP/RD Date: 12/01/2015
Company: Sergeant's Pet care Products, Inc.			
Original PRIA Due Date: 12/10/2015		Proposed New PRIA Due Date: 03/10/2016	
Previous Negotiated Due Dates:			
Is the "Fix" in-house? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected:	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input checked="" type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input checked="" type="checkbox"/> Product Chemistry	<input checked="" type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input checked="" type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
The acute toxicity to support these two identical formulations was classified as unacceptable. A 75-day deficiency letter was sent to the registrant on 10/22/2015. Registrant responded on 11/17/2015 with additional data and rationale to upgrade the study and justification for the unacceptable sources for basic and alternate formulations. Additional time is needed to review all this additional information.			
"75 Day" Letter sent? <input checked="" type="checkbox"/> Yes, Date sent 10/22/2015 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Time is needed to review the additional information submitted.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 12/09/2015

Decision #: 498686	Registration #: 2517-RTL	Petition #: N/A
498900	2517-RTA	

Issue(s) (describe in detail):

These two new pet care products, dog squeeze-on and cat spot-on, contain imidacloprid and pyriproxifen. The acute toxicity study was classified as unacceptable. In addition, some of the alternate source products for the two a.i. chemicals are not registered for use on pets, or are not similar in composition to the source products in the basic CSF, and need to be revised. A 75-day deficiency letter was sent to the registrant on 10/22/2015. Registrant responded on 11/17/2015, and submitted additional information and cited some other acute toxicity studies in his rationale to upgrade the unacceptable study. Similary, rationale was submitted to rebut our review of the alternate formulations, and alternate sources listed in the basic CSF. Additional time is needed to review all this information. We have had communications by e-mail and telephone with the registrant's agent.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-15335141349-RK

SUBMITTED on 12/04/2015 at 01:56:59 PM by CN=Rita Kumar/OU=DC/O=USEPA/C=US

APPROVED on 12/07/2015 at 09:30:53 AM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 12/07/2015 at 05:01:00 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 12/09/2015 at 07:35:30 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

Kumar, Rita

From: James Messina <jmessina@exponent.com>
Sent: Friday, December 04, 2015 1:11 PM
To: Kumar, Rita; Lewis, Marianne
Cc: Eagle, Venus; Kelly Hoskins (Kelly.Hoskins@perrigo.com); Carrie Daniels
Subject: PRIA Renegotiation

Dear Rita,

On behalf of our client, Sergeant's Pet Care Products, Inc. (Sergeant's), Exponent is submitting a PRIA due date renegotiation for the following pending registration actions:

- Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA File Symbol 2517-RTA)
- Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (EPA File Symbol 2517-RTL)

The current PRIA due date for both pending actions is December 10, 2015. As discussed, Sergeant's agrees to the new PRIA due date of March 10, 2016 for both actions. We appreciate the Agency's time and effort on both actions and look forward to working with EPA to complete both actions in as timely a manner as possible.

Please let me know if the Agency has any questions.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

e: jmessina@exponent.com | web: www.exponent.com

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Kumar, Rita

Resubmission:

From: James Messina <jmessina@exponent.com>
Sent: Wednesday, November 25, 2015 1:22 PM
To: Kumar, Rita
Cc: Kelly Hoskins (Kelly.Hoskins@perrigo.com); Nicola Cowen; Carrie Daniels
Subject: 2517-RTA Support Documents
Attachments: Offer to Pay_Imid + PPF Dogs_Hartz.pdf; Updated data matrix 2517-RTA_public.pdf; Updated data matrix 2517-RTA.pdf; 8570-34 Imid + PPF for Dogs.pdf

Dear Rita,

On behalf of Sergeant's Pet Care Products, Inc. (Sergeant's), Exponent is providing the following supporting documents for our November 17, 2015 EPA response letter to the Agency's 75 Day Deficiency Letter dated October 22, 2015 (Sergeant's Imidacloprid + Pyriproxyfen Spot on for Dogs) (EPA File Symbol 2517-RTA):

- Revised data matrix (EPA and public versions)
- Updated data citation form 8570-34
- Copy of the Offer to Pay letter sent to Hartz

Please see the attached information. We will deliver a hard copy to document processing on Monday.

Please let us know if you have any questions. Thank you.

Best Regards,

James Messina

Center Director and Principal Regulatory Consultant

Exponent[®], Inc | Center for Chemical Regulation and Food Safety

1150 Connecticut Ave., NW, Suite 1100

Washington, DC, United States of America

p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979

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Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

U.S. Registered Mail

November 17, 2015

The Hartz Mountain Corporation
C/O Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

**Subject: Offer to Pay Compensation Under FIFRA Section 3(c)(1)(F)
Sergeant's Pet Care Products, Inc. Proposed Product Sergeant's Imidacloprid +
Pyriproxyfen Squeeze On for Dogs ("Product")**

To Whom It May Concern:

As required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c)(1)(F), and implementing regulations at 40 CFR Part 152 Subpart E, Sergeant's Pet Care Products, Inc. ("Sergeant's") hereby notifies The Hartz Mountain Corporation, EPA Company Number 2596 ("COMPANY") that it intends to selectively cite data regarding imidacloprid and pyriproxyfen on file with the U.S. Environmental Protection Agency ("USEPA" or "Agency") related to your end-use products containing imidacloprid and pyriproxyfen to support the USEPA registration of an end-use Product containing the active ingredients.

According to the USEPA's Listing of Pesticide Data Submitters (dated October 30, 2015), Sergeant's has identified COMPANY as an Original Data Submitter who has end-use product data on file with the Agency for the active ingredients imidacloprid and pyriproxyfen.

Sergeant's hereby notifies COMPANY:

1. That it is the intent of Sergeant's to submit to the USEPA an application for pesticide registration for the Product containing the active ingredients imidacloprid and pyriproxyfen;
2. That Sergeant's offers to pay compensation regarding data, as appropriate, to COMPANY, with regard to the approval of this registration application, to the extent required by FIFRA Section 3(c)(1)(F); and
3. Sergeant's offers to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the selective citation of data listed in the enclosure.

If COMPANY intends to request compensation for the use of COMPANY's data, with regard to the approval of Sergeant's registration application, Sergeant's respectfully requests that COMPANY indicate, by return correspondence, the amount and terms of such requested



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

compensation. Please include the amount of any compensation previously received by COMPANY for the use of these data from other parties.

Sergeant's requests a response from COMPANY within 90 days from the date of this letter. If Sergeant's does not receive a response within 90 days, it will understand that no data compensation is requested by COMPANY.

If you have any questions, please contact me at 402-938-7079.

Sincerely,

A handwritten signature in cursive script that reads "Kelly R. Hoskins".

Kelly Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.



Selectively Cited Data

870.1100: Acute oral toxicity study with imidacloprid (9.1%)/pyriproxyfen (0.46%) spot on in rats (MRID 49287704)

870.1100: Acute oral toxicity study with imidacloprid (9.1%)/pyriproxyfen (0.46%) spot on in rats (MRID 49287804)



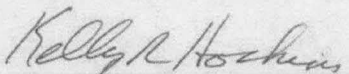
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: November 17, 2015		EPA Reg No./File Symbol: 2517-RTA		Page 1 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307	Sergeant's Pet Care Products	OWN	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096904	Bayer Animal Health	OLD	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.46%) Spot On in Rats	49287704	Hartz Mountain Corp.	PAY	
870.1100	Acute Oral Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.46%) Spot On in Rats	49287804	Hartz Mountain Corp.	PAY	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096905	Bayer Animal Health	PAY	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306	Sergeant's Pet Care Products	OWN	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 11/17/2015	




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: November 17, 2015		EPA Reg No./File Symbol: 2517-RTA		Page 2 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096907	Bayer Animal Health	PAY	
870.2500	Primary Dermal Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096908	Bayer Animal Health	PAY	
870.2600	Dermal Sensitization Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On	45096909	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Seven Week Old Puppies	45097101	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Adult Dogs	45097102	Bayer Animal Health	PAY	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORTJAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer Animal Health	OLD	
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs	43679609	Bayer Animal Health	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs	43679610	Bayer Animal Health	OLD	
810.3300	A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Animal Health	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date 11/17/2015	



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Date: November 17, 2015	EPA Reg No./File Symbol: 2517-RTA	Page 3 of 3
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs	
Ingredients: Imidacloprid, Pyriproxyfen		

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy

Kumar, Rita

Resubmission:
S 978464
2517-RTA

From: James Messina <jmessina@exponent.com>
Sent: Tuesday, November 17, 2015 5:08 PM
To: Kumar, Rita
Cc: Eagle, Venus; Kelly Hoskins (Kelly.Hoskins@perrigo.com); 'Mark Levin'; Mary Hunt
Subject: 75-Day Deficiency Responses
Attachments: EPA Deficiency Letters.pdf; 2517-RTA -RTL Deficiency Responses and Attachments Final 11-17-2015.pdf

Dear Rita,

On behalf of our client, Sergeant's Pet Care Products, Inc., Exponent is responding to EPA's two 75-day deficiency letters dated October 22, 2015 (attached) for the following two pending registration applications:

- Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (EPA File Symbol 2517-RTA)
- Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (EPA File Symbol 2517-RTL)

The attached EPA issued deficiency letters for each product and the deficiencies were identical for both. The attached response letter supports both applications and addresses the EPA questions and includes supporting documentation (i.e., EPA approved TGA labels, EPA guidance documents). The response itself is only 9 pages and the rest of the submission contains supporting documentation. The submission specifically provides data to upgrade the acute oral toxicity study to acceptable and to address the product chemistry (i.e., CSF, TGA) questions. We think that the EPA review will include Dr. Backus and yourself, so it should be limited to the RD team.

We request that EPA review the attached response under the current PRIA due date of December 10, 2015 for both pending actions. We understand that the Agency is busy, but we hope that it can understand the importance of these actions to our clients business. Can you please let us know if review within the current PRIA timeframe is possible?

We will deliver an official copy to document processing tomorrow morning.

Please let me know if you have any questions.

Best Regards,

James Messina
Center Director and Principal Regulatory Consultant
Exponent[®], Inc | Center for Chemical Regulation and Food Safety
1150 Connecticut Ave., NW, Suite 1100
Washington, DC, United States of America
p: 202-772-4932 | c: 301-908-1181 | f: 202-772-4979
e: jmessina@exponent.com | web: www.exponent.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Rita Kumar

From: Jacquelyn Marchese *Jacquelyn Marchese*

Secondary Review: Kevin Sweeney *Kevin J. Sweeney*

Date: November 12, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

~~THIS DER DOES CONTAIN CONFIDENTIAL BUSINESS INFORMATION~~

Note: MRIDs found to be unacceptable to support label claims should be removed from the data matrix.

DP barcode: 427198

Decision no.: 498900

Submission no: 962169

Action code: R315

Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

EPA Reg. No or File Symbol: 2517-RTA

Formulation Type: liquid

Ingredients statement from the label with PC codes included:

Imidacloprid 9.10% PC: 129099

Pyriproxyfen 0.46% PC: 129032

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

Weight of dog (lb)	Amount of product (mL)	mL/kg of imidacloprid	mL/kg of pyriproxyfen	Mg/kg of product	Mg/kg of imidacloprid	Mg/kg of pyriproxyfen
3-10	0.4 mL	0.008-0.026	0.0004-0.001	97-322	8-29	0.44-1.48
11-20	1 mL	0.01-0.018	0.0005-0.000938	121-219	11-19	0.556-1
21-55	2.5 mL	0.009-0.02	0.00046-0.0012	108-283	9.8-25	0.49-1.3
55 +	4.0 mL	0.0146	0.00037	175	15	0.805

*Based on 1.097 g/cm³ density

Use Patterns: This product is to be applied to dogs over the age of 7 weeks, weighing over 3 lbs. The label directs the user to apply the product in three different ways:

- directly to the skin of the dog from the back of the neck to a point midway between the neck and tail
- as a spot on the dog's back between the shoulder blades
- as a stripe starting at the middle of the back and ending between the shoulder blades

I. Action Requested: This Sergeant's product was submitted as an R315, new end use, non-food animal product. The proposed label has public health claims of kills fleas (eggs, larvae and adult), prevents flea egg hatch/development, stops the flea lifecycle, controls/kills fleas for up to 1 month, etc. The reviewer requested that the seven submitted efficacy studies be reviewed to determine their applicability in support of the new product and the proposed label claims.

II. Background: The registrant has cited seven previously reviewed efficacy studies to support the registration of this new product and the claims against fleas.

III. MRID Summary:

43679609. Cunningham, J. 1995. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for control of Fleas on Dogs.

(1) GLP

(2) Methods:

On study day-3, 32 adult dogs of various breed, sex, and length of hair were initially infested with 100 fleas each to screen their ability to host the pest. On day -2, fleas were combed out and counted, and dogs were then separated into four groups of 8 dogs. Three out of the four groups were given Bay t 7391, a 10% imidacloprid solution, at various rates. Group 1 received of 3.75 mg/kg of imidacloprid, group 2 received 7.5 mg/kg of imidacloprid, and group 3 received 10.0 mg/kg of imidacloprid. The last group received a blank control substance. All treatments were administered with a syringe and was applied to the skin between the shoulder blades. Each dog was infested with approximately 100 adult fleas on days -1, 6, 13, 20, 27, and 33. Fleas were visually counted on days 1, 7, 14, 21, and 28 and were combed out and counted on day 34. Percent control was calculated by subtracting the number of fleas counted on the treated animals from the number of fleas counted on the control animals, divided by the number of fleas counted on the control animals.

(3) Results:

DAY	GROUP 1 3.75 mg/kg		GROUP 2 7.5 mg/kg		GROUP 3 10.0 mg/kg		GROUP 4 UNTREATED
	TOTAL	CONTROL	TOTAL	CONTROL	TOTAL	CONTROL	TOTAL
1	17	96.9	12	97.8	4	99.3	553
7	7	99.0	0	100	0	100	751
14	51	94.4	9	99.0	1	99.9	911
21	30	96.8	12	98.7	0	100	953
28	40	95.4	14	98.4	6	99.3	873
34	98	91.6	28	97.6	36	96.9	1171

(4) Conclusion: This study is **acceptable** and demonstrates that imidacloprid, when applied to dogs at the rate of 3.75 mg/kg, controls existing flea populations and continues to control fleas for up to 34 days.

43679610. Cunningham, J.; Everett, R.; 1994. Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs.

(1) non-GLP

(2) **Methods:** Thirty-seven adult dogs of various breed and hair lengths were initially selected for the study. On day -2, dogs were infested with 100 male and female adult fleas. Fleas were combed out, counted, and removed on day -1. Thirty dogs (18 female, 12 male) were then chosen based on their ability to harbor fleas and were divided into 3 groups of 10. The first group received an 8.5% imidacloprid solution at the rate of 0.1 mL of imidacloprid/kg directly between the shoulder blades, the second group received a 5.0% imidacloprid solution 0.2 mL/kg of imidacloprid, half between the shoulder blades and half on the romp, and the third received a placebo on two unspecified locations. All treatments were received by applying the solution directly to the skin. Dogs were then infested with 100 fleas each on days 6, 13, 20, 27, and 34. Fleas were counted on days 1, 7, 14, 21, and 28, and were combed out and counted on days 35 and 42. Percent control was calculated using Abbott's formula, by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

Fleas

total fleas and percent control of fleas were as follows:

<u>Day</u>	<u>GROUP 3</u>	<u>GROUP 2</u>		<u>GROUP 1</u>	
	<u>Untreated</u>	<u>5% NTN</u>	<u>%</u>	<u>8.5% NTN</u>	<u>%</u>
	<u>Total</u>	<u>Total</u>	<u>Control</u>	<u>Total</u>	<u>Control</u>
1	494	0	100	0	100
7	632	0	100	2	99.7
14	728	27	96	13	98
21	806	19	98	20	98
28	676	40	94	22	97
35	1174	82	93	75	94
42	689	162	76	235	66

(4) **Conclusion:** This study is **unacceptable** because the tested amount of imidacloprid per kg of body weight is higher than the labeled rate of imidacloprid for this product.

44256901. Cruthers, L.; 1997. Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs

(1) GLP

(2) **Methods:** Thirty adult, mix-breed dogs of both sexes were selected for the study. Dogs were separated into 3 groups of 10 (X, Y, or Z). On test day 0 each group received a different treatment. Members of group X received Advantage (9.1% Imidacloprid), group Y received Frontline Top Spot (9.7% fipronil) and members of Group Z received the Advantage blank vehicle. The products were applied to the dogs per the labeled application rate. The application rate of Advantage mimicked the application rate of the proposed product (minimum of 0.008 mL/kg). On days -1, 6, 13, 20, and 27 dogs were infested with approximately 100 adult cat fleas. Two dogs from each group were examined and fleas were evaluated to be dead, alive or moribund on 2, 4, 8, 12, and 24 hours post treatment. All alive and moribund fleas were gathered and held in a separate container for 24 hours to determine mortality. Further, all fleas collected were dissected and evaluated for blood ingestion to determine if treatment prevented fleas from biting. Efficacy was calculated by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS*
TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	10	6	60.0
	TOP SPOT	8	6	75.0
	CONTROL	0	0	-
4 HRS	ADVANTAGE	15	15	100
	TOP SPOT	5	2	40.0
	CONTROL	3	1	33.3
8 HRS	ADVANTAGE	151	101	66.9
	TOP SPOT	165	115	69.7
	CONTROL	0	0	-
12 HRS	ADVANTAGE	99	88	88.9
	TOP SPOT	140	93	66.4
	CONTROL	1	1	100
24 HRS	ADVANTAGE	145	99	68.3
	TOP SPOT	169	153	90.5
	CONTROL	12	12	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 0

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	130	78	60.0
	TOP SPOT	116	40	34.5
	CONTROL	179	137	76.5
4 HRS	ADVANTAGE	100	85	85.0
	TOP SPOT	112	38	33.9
	CONTROL	174	122	70.1
8 HRS	ADVANTAGE	22	20	90.9
	TOP SPOT	11	7	63.6
	CONTROL	195	103	52.8
12 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	177	138	78.0
24 HRS	ADVANTAGE	0	0	-
	TOP SPOT	0	0	-
	CONTROL	180	142	78.9

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 0

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	57	7775	52	18175	86
	15081	73	10825	64	11631	93
	MEAN	65.0	MEAN	58.0	MEAN	89.5
	% CONTROL	27.4	% CONTROL	35.2	% CONTROL	-
4 HRS	16012	66	17206	64	HIEMBY	84
	15025	34	18604	48	15161	90
	MEAN	50.0	MEAN	56.0	MEAN	87.0
	% CONTROL	42.5	% CONTROL	35.6	% CONTROL	-
8 HRS	11698	0	18336	2	17526	98
	16744	22	HHCAYJ	9	18561	97
	MEAN	11.0	MEAN	5.5	MEAN	97.5
	% CONTROL	88.7	% CONTROL	94.3	% CONTROL	-
12 HRS	EFMGG	0	18393	0	15783	87
	2863	0	HHFMRW	0	14802	90
	MEAN	0	MEAN	0	MEAN	88.5
	% CONTROL	100	% CONTROL	100	% CONTROL	-
24 HRS	15185	0	245	0	13995	100
	15737	0	HHFMRX	0	14368	80
	MEAN	0	MEAN	0	MEAN	90.0
	% CONTROL	100	% CONTROL	100	% CONTROL	-

BLOOD DETECTED IN THE BODIES OF DEAD FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. DEAD FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	44	40	90.9
	TOP SPOT	14	11	78.6
	CONTROL	14	12	85.7
4 HRS	ADVANTAGE	87	63	72.4
	TOP SPOT	90	65	72.2
	CONTROL	7	5	71.4
8 HRS	ADVANTAGE	67	48	71.6
	TOP SPOT	74	56	75.7
	CONTROL	12	12	100
12 HRS	ADVANTAGE	72	44	61.1
	TOP SPOT	94	54	57.4
	CONTROL	7	3	42.9
24 HRS	ADVANTAGE	87	69	79.3
	TOP SPOT	59	45	76.3
	CONTROL	10	10	100

* DEAD FLEAS RECOVERED FROM THE DOGS DURING COMBING OR FROM PANS BENEATH THE DOGS.

BLOOD DETECTED IN THE BODIES OF LIVE FLEAS*
TEST DAY 27

TIME INTERVAL	TREATMENT	TOTAL NO. LIVE FLEAS RECOVERED	NO. OF FLEAS WITH BLOOD	PERCENT POSITIVE FOR BLOOD
2 HRS	ADVANTAGE	49	40	81.6
	TOP SPOT	65	30	46.1
	CONTROL	105	105	100
4 HRS	ADVANTAGE	2	2	100
	TOP SPOT	4	4	100
	CONTROL	128	91	71.1
8 HRS	ADVANTAGE	0	0	-
	TOP SPOT	3	2	66.7
	CONTROL	128	91	71.1
12 HRS	ADVANTAGE	17	14	82.3
	TOP SPOT	6	2	33.3
	CONTROL	92	89	96.7
24 HRS	ADVANTAGE	2	2	100
	TOP SPOT	3	3	100
	CONTROL	110	69	62.7

* LIVE FLEAS RECOVERED FROM THE DOGS DURING COMBING AND HELD FOR 24 HOURS BEFORE EXAMINATION FOR BLOOD.

LIVE FLEAS RECOVERED FROM DOGS AND PERCENT FLEA CONTROL
TEST DAY 27

TIME INTERVAL	ADVANTAGE		TOP SPOT		CONTROL	
	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS	DOG NO.	NO. LIVE FLEAS
2 HRS	6823	4	7775	35	18175	64
	15081	45	10825	30	11631	41
	MEAN	24.5	MEAN	32.5	MEAN	52.5
	% CONTROL	53.3	% CONTROL	38.1	% CONTROL	-
4 HRS	16012	0	17206	0	HIEMBY	62
	15025	2	18604	4	15161	66
	MEAN	1.0	MEAN	2.0	MEAN	64.0
	% CONTROL	98.4	% CONTROL	96.9	% CONTROL	-
8 HRS	11698	0	18336	1	17526	67
	16744	0	HHCAYJ	2	18561	61
	MEAN	0	MEAN	1.5	MEAN	64.0
	% CONTROL	100	% CONTROL	97.7	% CONTROL	-
12 HRS	EFMGG	0	18393	0	15783	54
	2863	17	HHFMRW	6	14802	38
	MEAN	8.5	MEAN	3.0	MEAN	46.0
	% CONTROL	81.5	% CONTROL	93.5	% CONTROL	-
24 HRS	15185	2	245	1	13995	49
	15737	0	HHFMRX	2	14368	61
	MEAN	1.0	MEAN	1.5	MEAN	55.0
	% CONTROL	98.2	% CONTROL	97.3	% CONTROL	-

(4) Conclusion: This study is partially acceptable. The study supports that imidacloprid, when applied to a dog at

0.008 mL/kg kills fleas (87.76 mg/kg). The data do not support claims that imidacloprid prevents fleas from biting a dog. Also, time based claims are supported by showing statistical significance which is not prevented here and are thus not supported.

44256902. Hopkins, T.; Woodley, I.; Gyr, P.; 1997. Imidacloprid Topical Formulation: Larvicidal Effect Against *Ctenocephalides felis* in the Surroundings of Treated Dogs.

(1) non-GLP

(2) **Methods:** This MRID consists of two studies. The first study only tested 4 dogs, while the second study tested 7 dogs in 2 groups.

Entomologist's note: In order to receive meaningful statistical results from a study, the minimum number of dogs recommended to test in one group is 6. Therefore, these studies will not be considered due to insufficient replication and statistical power.

(3) **Results:** As too few test animals were studied in these tests, the results will not help support the subject product of this review.

(4) **Conclusion:** As stated above, this MRID is **unacceptable** because of too few replicates in the study design. No claims can be supported with this test.

44256903. Cunningham, J. 1997. Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs.

(1) GLP

(2) **Methods:** Twenty-four adult, mixed-breed dogs were randomly assigned to 3 groups. On day 0, groups 1 and 2 were treated with Advantage solution (9.1% imidacloprid), per label instructions. (Dogs in group 1 received an average imidacloprid dose of 16 mg/kg, and dogs in group 2 received an average imidacloprid dose of 14.5 mg/kg). Group 3 served as the control and received a placebo treatment. Imidacloprid treatment was administered depending on the weight of the dog. Dogs 20 pounds and under received the treatment between the shoulder blades, and dogs weighing 21 pounds and over received the treatment in 3-4 even spots along the back from the top of the shoulder to the base of the tail. Each dog was infested with 100 unfed adult fleas on days -1, 6, 13, 20, 27, and 34. Live fleas remaining on each dog were counted and removed on days 1, 7, 14, 21, 28, and 35. On day 4, group 1 dogs were shampooed with an emollient shampoo (Allegroom Virbac) and rinsed. Group 2 dogs were immersed in a tank of water for one minute. Half of group 3 dogs were shampooed and the other half were immersed in water. The water immersion treatment was repeated on the same dogs on days 11, 18, 25, and 32.

Percent control was calculated using Abbott's formula, by subtracting the average number of fleas counted on the treated animal from the average number of fleas counted on the untreated animals divided by the average number of fleas counted on the untreated animal.

(3) **Results:**

GROUP 1 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING ON DAY 4

DOG NO.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
202	80	0	15	17	30	17	32
315	62	0	0	1	4	1	15
353	76	0	0	0	2	1	20
369	97	0	0	0	0	0	5
401	86	0	0	3	18	11	39
497	89	0	0	1	0	0	33
523	104	0	12	35	27	19	48
526	78	0	0	0	10	13	54
TOTAL	672	0	27	57	91	62	246
MEAN	84.0	0.0	3.4	7.1	11.4	7.8	30.8
% CONTROL	-	100	96.2	92.5	88.1	92.2	65.5

GROUP 2 - ADVANTAGE TREATMENT (DAY 0) FOLLOWED BY WATER IMMERSION ON DAYS 4, 11, 18, 25, 32

DOG No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
201	103	0	0	0	8	15	31
313	71	0	0	2	4	11	18
341	79	0	0	0	4	0	10
357	76	0	0	0	0	0	8
386	85	0	2	4	43	48	52
394	100	0	0	1	13	1	35
440	90	0	0	0	1	0	1
451	73	0	0	0	0	0	3
TOTAL	677	0	2	7	73	76	158
MEAN	84.6	0.0	0.3	0.9	9.1	9.5	19.8
% CONTROL	-	100	99.6	99.0	89.7	88.8	78.7

GROUP 3 - CONTROL - PLACEBO TREATMENT (DAY 0) FOLLOWED BY SHAMPOOING OR WATER IMMERSION

DOG No.	NUMBER FLEAS / DOG						
	DAY						
	-2	1	7	14	21	28	35
228a	69	93	101	96	89	106	91
298a	86	103	96	101	96	104	96
442a	80	78	90	80	95	93	82
450a	108	106	75	103	103	99	88
Total	343	380	362	380	383	402	357
Mean	85.8	95.0	90.5	95.0	95.8	100.5	89.3
336b	78	74	76	93	82	95	83
368b	91	55	49	88	80	86	95
371b	71	68	91	63	85	68	90
383b	84	71	90	105	105	89	103
Total	324	268	306	349	352	338	371
Mean	81.0	67.0	76.5	87.3	88.0	84.5	92.8

a - Dogs shampooed on day 4.

b - Dogs immersed in water on days 4, 11, 18, 25, 32.

(4) Conclusion: This study is unacceptable, as imidacloprid is tested at a rate of 14.5 mg/kg which is higher than

the minimum imidacloprid rate of 9.8 mg/kg on the label. Further, as the water immersion and shampooing test is not stringent enough. For a full shampooing claim, animals must be shampooed and rinsed for 5 minutes, while for a water-proof test only, dogs must be immersed for 1 minute.

45086801. Donahue, W.; Meola, S.; Palma, K., et al. 2000. Nylar 50 (percent) Concentrate: Product Performance /Efficacy Reports.

(1) non-GLP

(2) **Methods/Results:** The first two studies evaluated the efficacy of dip and shampoo treatments on cats. These studies tested pyriproxyfen against adult cat fleas and eggs. **These studies do not support public health claims for Sergeant's Imidacloprid + Pyriproxyfen Squeeze on for Dogs, because data on cats cannot be bridged to support a dog spot-on product, and only 5 cats were tested per study, too few to provide statistically meaningful results.**

The third study examined egg mortality by placing 50 fleas in a 10 mg vial treated with $0.25\mu\text{g}/\text{cm}^2$ pyriproxyfen for 24 hours. Fleas were then removed, and placed on one of 2 cats. Forty-six hours after treatment, fleas began to lay eggs containing yolk and 70 hours after treatment, flea eggs were normal. Researchers in this study did not allow eggs to hatch, rather they evaluated the eggs through dissection. Using a microscope, eggs were carefully cut open and the inside contents were then evaluated for egg viability. Pyriproxyfen at low doses, did not prevent the laying of eggs and although egg viability was evaluated through dissection, researchers did not follow any eggs for enough time to determine if any were able to develop into viable offspring. Witnessing the egg hatch is needed to make a true determination of egg viability. **Further, this study was conducted on cats and therefore is not applicable to a dog spot-on product.**

The fourth study was an *in-vitro* study in which flea eggs were exposed to 9 cm diameter (63.6 cm^2 area) filter paper treated with pyriproxyfen at the rate of $1.1\mu\text{g}/\text{cm}^2$. Filter paper on average weighed 460 mg. Control papers were treated with alcohol. Eggs were divided into 5 groups of 20 replicates and were exposed for varying times depending on the age of the egg. If the egg was between 0-4 hours old, it would receive a treatment of either 1 minute, 10 minutes, or 60 minutes. A 24 hour old egg would be exposed for a time of 1 minutes, 30 minutes, or 60 minutes, and a 48 hour old egg would receive a treatment for 1 min, 30 minutes, or 60 minutes. After the assigned exposure time, eggs were transferred to a clean filter paper with a larval feeding diet. After 5 days, hatch percentage was determined and after 4 weeks, the percent of eggs that developed into adults was determined. **This study is not applicable to the proposed product as filter paper received a rate of 152 mg/1kg of pyriproxyfen, a rate that is higher than the labeled rate.**

The next study was also an *in-vitro* study in which exposed eggs to pieces of dog hair (obtained from a groomer). In the non-negative control groups, each piece of dog hair received 1 mL treated with 0.125 % pyriproxyfen, while the control hair pieces were treated with isopropyl alcohol. Each piece of hair was approximately 460 mg which equated to a treatment rate of roughly 152 mg/1 kg. After treatment, 100 eggs were divided into 5 groups and were exposed to pieces of hair for 1 minute, 10 minutes, 30 minutes, or 60 minutes. After exposure, eggs were transferred to a clean holding area and were observed to determine percent hatch and eventually percent adult emergence. This study was replicated 1 day, 2 months, 4 months, and 6 months after treatment. **The study is also not acceptable for this product as the tested rate of pyriproxyfen is higher than the intended label rate.**

The next study was also an *in-vitro* tested adult fleas on treated filter paper. Groups of 20 adult fleas were collected from breathing on 7-10 day old cocoons. Each group was separated into 0.5 liter glass canning jars containing either pyriproxyfen treated or acetone treated filter paper and held for 10 days. Mortality was evaluated and compared to control jars daily. Ninety percent mortality was reached after forced flea exposure for 7 days. **As ninety percent mortality needs to be demonstrated by the fourth day of forced exposure, this study is supplemental.**

The next study (*in-vitro*) tested blood-fed 5 day old adult fleas. Fleas were placed in 5 cm diameter cages and fed blood using an "artificial dog" feeding system. Cages were lined with dog hair treated with pyriproxyfen at a rate of $352\mu\text{g}/\text{gram}$ of dog hair. This is equivalent to 0.352 mg/1 kg. Hair in the control cages were treated with 5ml of

acetone. Hair dried for 2 hours in a fume hood before placement in the 5 replication cages. One hundred adult fleas were placed in each on cage. Fleas rested on dog hair in close proximity to a parafilm membrane where they were fed warm bovine blood. Cages were checked daily for mortality of dead fleas for 9 days. Mortality of fleas reached 90% 7 days after treatment. **The rate of mortality should reach 90% by day 4. This study is also supplemental.**

Flea eggs of different ages were exposed *in-vitro* to filter paper treated with 1.1 µg of pyriproxyfen / cm³. The three groups of eggs were placed on the treated or control papers at 0-4 hours, 24 hours, and 48 hours. Each subgroup was removed at their designated time interval and placed in a clean container with larval diet. Eggs were observed and hatch rate was determined for 5 days post removal from treatment. For eggs aged 24 hours or less, a 2 hour exposure of pyriproxyfen was enough to limit percent hatch to a high of 9%, though 22% hatch was observed with 48 hour-old eggs exposed to pyriproxyfen for 2 hours. Although a rate of pyriproxyfen is given for this study, it is not applicable to the rate of the proposed product, Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, which provides pyriproxyfen rates in mg/kg of body weight for a dog. **This study is supplemental.**

(3) Conclusion: This MRID is **supplemental**, it consisted of 8 studies with varying methods. Six out of the 8 studies were *in-vitro* studies instead of *in-vivo*. The two *in-vivo* studies had insufficient replication to support meaningful statistical results, while the *in-vitro* studies were at best supplemental as they only documented activity of pyriproxyfen on treated hair or surfaces and the rates used for these studies are not relatable to the labeled rate of mL/lb (or mg/kg for this review). The data generated from these studies, for reasons described above do not support "kills fleas" or IGR claims on the label of the proposed product.

47190401. Doyle, J.; Egan, T.; 2006. A Controlled Randomized Study to Evaluate the Efficacy of Advantage Against A Natural Infestation of Dog Lice (*Trichodectes canis*) Following a Single Topical Administration to Adult Mixed Breed Dogs.

This MRID consisted of 3 studies that tested the efficacy of imidacloprid against lice on dogs. As the subject product of this review is for fleas, this study is **unacceptable** and does not support any proposed claims on the label.

IV. EXECUTIVE DATA SUMMARY:

(A) Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs is a proposed dog spot-on product for the control of fleas. The product will be packaged and marketed to various sizes of dogs based on weight. The lowest labeled application rate of active ingredient that will be marketed is proposed to be 8 mg/kg of imidacloprid and 0.44 mg/kg of pyriproxyfen. The combination of studies submitted support that the product, when applied to dogs, is efficacious against adult and larval cat fleas. Although promising results were presented from *in-vitro* studies using pyriproxyfen against flea eggs, inapplicable rates and lack of *in-vivo* testing on dogs prevented the use of these data for this product.

V. LABEL RECOMMENDATIONS:

(1) No changes for the Directions for Use are suggested. Please note this section describes slight variations in application of the product to the dog. These variations will not affect the efficacy of the product against fleas.

(2) The following marketing /product performance claims are acceptable:

- Prevents [further] flea infestation for 1 month (or equivalent)
- Protects against further infestation
- Kills fleas and may reduce the incidence of hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.
- Kills flea larvae
- Apply monthly to control and prevent fleas
- Apply monthly for optimal flea control and to prevent fleas
- Continues to kill fleas for 4 weeks

- Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
- Active against fleas
- Kills fleas on puppies and dogs
- Offers protection against fleas
- Flea control
- Controls fleas which can serve as an intermediate tapeworm host
- Prevents the development of flea larvae into biting adult fleas
- Contains pyriproxyfen an insect growth regulator in addition to imidacloprid
- This product is a flea larvicide and adulticide
- Provides multi-stage flea control

(3) The following marketing claims are unacceptable:

- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Kills flea larvae in treated dog's surroundings [following contact with treated dog]
- Protects against irritating flea bites
- Protects against the infestation and reinfestation of the home by fleas on treated dogs
- Complete flea protection
- Optimal flea control
- Optimal flea protection
- Advanced flea protection
- Breaks the flea life cycle
- Waterproof
- Remains effective even after bathing, shampooing, water immersion, rain, swimming
- Kills fleas in 12 hours
- Controls problems associated with fleas
- Prevents flea eggs from hatching
- Prevents flea eggs from developing into biting adult fleas
- Kills flea adults, larvae, and eggs providing three-way protection
- Controls flea eggs
- Kills flea eggs
- Targets/controls all stages of flea lifecycle
- This product is a flea ovicide
- Prevents all stages of the flea life cycle from developing
- Inhibits the immature flea life stages from developing, preventing them from becoming biting adult fleas.
- Controls existing flea eggs
- Original vet strength
- Fast acting
- Remains effective after exposure to sunlight

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 43679610, 45086801, 47190401.

(5) These studies support that the minimum rate of imidacloprid that is efficacious is 10 mg/kg. If the dog is over 97 pounds this will no longer be the case. We suggest the highest weight class be revised to 55-97 lbs.

~~CONFIDENTIAL APPENDIX~~

MRIDs 44256901, 44256902, 44256903, and 45086801 support claims on the me-tooed products 11556-125, 11556-127, 11556-128, and 11556-130. Specifically, the acceptable claims based on the me-tooed product are:

- Waterproof
- Remains effective even after bathing, shampooing, water immersion, rain, swimming
- Kills fleas in 12 hours
- Kills fleas within 12 hours
- Kills reinfesting fleas within 2 hours
- Kills/controls flea eggs
- Kills all flea life stages
- Complete flea protection
- Optimal flea control
- Optimal flea protection
- Advanced flea protection
- Breaks the flea life cycle
- Kills fleas in 12 hours
- Prevents flea eggs from hatching
- Prevents flea eggs from developing into biting adult fleas
- Kills flea adults, larvae, and eggs providing three-way protection
- Controls flea eggs
- Kills flea eggs
- Targets/controls all stages of flea lifecycle
- This product is a flea ovicide
- Prevents all stages of the flea life cycle from developing
- Inhibits the immature flea life stages from developing, preventing them from becoming biting adult fleas.
- Controls existing flea eggs

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, October 22, 2015 5:24 PM
To: 'James Messina'
Subject: FW: 2517-RTA deficiency letter
Attachments: image2015-10-22-172303.pdf

Dear Jim: Please see attached 75-day deficiency letter for the subject product.
Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OCT 22 2015

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

OPP Decision Number: D-498900

Registrant Name: Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.

Registrant Address: 10077 South 134th Street
Omaha, NE 68138-3710

Authorized Agent: James B. Messina
Exponent, Inc.
1150 Connecticut Avenue, NW, Suite 1100, Washington, DC, 20036

Subject: Data Deficiency

Product Name: Sergeant's Imidacloprid + Pyriproxifen Squeeze On for Dogs

EPA File Symbol: 2517-RTA

Application Date: 12/23/2014

EPA Receipt Date: 12/24/2014

PRIA Date: 12/10/2015

Dear Ms. Hoskins:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending January 5, 2016 to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to

meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The acute oral toxicity study in MRID 49510307 has been reviewed and classified as supplementary. Although 3/5 rats dosed at 1500 mg/kg survived, there is no mention (or guidance) for a limit dose of 1500 mg/kg in either the OECD or OCSPP (OPPTS) Guidelines and for a limit dose at 2000 mg/kg the OECD guidance is: "Dose one animal at the test dose. If the animal dies, conduct the main test to determine the LD50." In addition, previous testing (MRID 45096904) of a toxicologically similar formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen gave LD50 values of 1283 mg/kg for males (95% confidence limits were 680 to 1678 mg/kg) and 1000 mg/kg for females (95% confidence limits were incalculable). Based on these considerations, we cannot accept an LD50 > 1500 mg/kg from the results of this study, which should have defaulted to the up-and-down procedure after the death of the rat which was dosed at 2000 mg/kg.

A new oral acute toxicity study is needed to define the acute toxicity profile for this product.

2. As indicated above, we are not able to establish an acute oral toxicity of >1500 mg/kg from submitted data. Therefore child resistant packaging certification would be needed unless a new acute toxicity study demonstrates that the product has an acute oral toxicity LD50 greater than 1.5 g/kg.
3. As described on the Agency's website for pet spot-on products, <http://www2.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects#report>, and in light of the large number of adverse pet incidents (for which inert ingredients could be a contributor), EPA has determined that only one basic Confidential Statement of Formula (CSF) would generally be allowed for new spot-on products so that incidents could be more easily evaluated on a product-by-product basis to assess whether particular formulations caused more incidents than others. EPA sees no reason to depart from that position for this product and therefore only one basic CSF is acceptable.

While the make-up of the formulation cannot be changed, EPA does allow registrants to use alternate sources for the active or inert ingredients so long as they remain within the same certified limits for each ingredient. Those alternative sources can be identified either in an attachment to the basic CSF or in an alternate CSF.

Based on the information above, alternate CSF #1 dated 3/2/15 is not acceptable because it lists several alternate technical sources that are not within the same certified limits.

4. Further, the technical source product(s) that are listed on the basic Confidential Statement of Formula (attachment or alternate CSF as specified above) must either 1) be registered for companion animal use or 2) allow for "any other uses for which EPA has accepted the required data and/or citations of data." If neither of these conditions are satisfied, the technical may not be used to formulate the end-use product.

For technical sources that are not registered for companion animal use but allow for "other use for which EPA has accepted the required data and/or citations of data" acceptable companion animal data must be submitted or cited on the data matrix for this product.

- Currently, one of the technical sources listed on the basic CSF is not registered for companion animal use. The data matrix provided for this product does not address the companion animal data requirements.
- Additionally, there are several listed technical sources found on alternate CSF #1 that are not registered for companion animal use.

Therefore, the CSFs need to be revised. The only acceptable sources would be sources that have a companion animal use or sources that allow for "other uses for which EPA has accepted the required data and /or citations of data. Sources that have neither must be deleted. Should you wish to use technical sources that allow for other uses that are not specifically listed on the technical, then you must submit a revised data matrix that addresses the generic data for companion animals and a revised certification with respect to citation of data form (8570-34) with the same date of the revised data matrix.

5. Based on the information above and how data compensation is addressed, a revised Formulator's Exemption form may be required.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

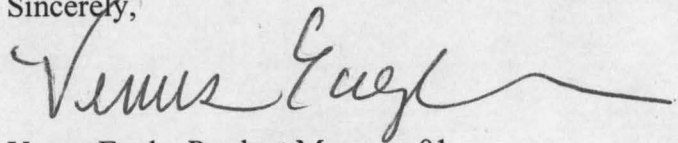
This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on December 10, 2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than November 25, 2015 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than November 25, 2015 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.

3. **Not respond.** If the Agency does not hear from you by November 25, 2015, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by Nov. 25, 2015 by contacting kumar.rita@epa.gov, in the course of the hours of 8:00 am to 5:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Venus Eagle". The signature is fluid and extends to the right with a long horizontal stroke.

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Acute toxicity review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

September 18, 2015

MEMORANDUM:

Subject: Name of Pesticide Product: SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN
SQUEEZE ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTA
DP Barcode: DP 427196
Decision No.: 498900
Action Code: R315
PC Codes: 129099 (Imidacloprid: 9.10%)
129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist *Byron T. Backus*
CITAB *Sept - 18 - 2015*
Registration Division (7505P) *JCR*

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

To: Rita Kumar RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
<u>Other Ingredients:</u>	<u>90.44%</u>
TOTAL	100.00%

ACTION REQUESTED: "...Please provide a...full review of cited data to support registration of this me-too new registration application for a dog pour-on product..."

COMMENTS AND RECOMMENDATIONS:

1. To satisfy the acute toxicity data requirements, the registrant is citing (data matrix dated December 23, 2014) the following MRIDs: 49510307 (acute oral toxicity study with CVSG 003; a study submitted for EPA File Symbol 2517-RTA); 49510306 (an acute inhalation LC₅₀ study waiver request submitted by Sergeant's Pet Care Products); 45096905 (an acute dermal toxicity study in rats); 45096907 (a primary eye irritation study in rabbits [not rats as indicated in the data matrix]); 45096908 (a primary dermal irritation study in rabbits [not rats as indicated in the data matrix]); and 45096909 (a dermal sensitization study in guinea pigs [not rats as indicated in the data matrix]); the last four cited studies were conducted on a formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen, and were originally submitted to the Agency as supporting data for the Bayer products now registered under EPA Reg. Nos. 11556-125 through -130). These studies have been previously reviewed (TXR 5001579, dated August 30, 2000).
2. The registrant's cover letter dated December 23, 2015 includes the following:

"Please note, although this new end-use product is very similar to the EPA registered products Advantage II for Dogs, EPA Reg. Nos. 11556-128, -125, -127, and -130, the formulation is somewhat different, as demonstrated by the acute toxicity of this new end-use product. The acute toxicity of this new end-use product does not meet any of the toxicity criteria specified in 40 CFR 157.22, and thus does not require Child Resistant Packaging."
3. The acute oral toxicity study in MRID 49510307 has been reviewed and classified as supplementary. Although 3/5 rats dosed at 1500 mg/kg survived, there is no mention (or guidance) for a limit dose of 1500 mg/kg in either the OECD or OCSPP (OPPTS) Guidelines and for a limit dose at 2000 mg/kg the OECD guidance is: "Dose one animal at the test dose. If the animal dies, conduct the main test to determine the LD₅₀." In addition, previous testing (MRID 45096904) of a toxicologically similar formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen gave LD₅₀ values of 1283 mg/kg for males (95% confidence limits were 680 to 1678 mg/kg) and 1000 mg/kg for females (95% confidence limits were incalculable). Based on these considerations, we cannot accept an LD₅₀ > 1500 mg/kg from the results of this study, which should have defaulted to the up-and-down procedure after the death of the rat which was dosed at 2000 mg/kg.
4. The registrant has requested a waiver (in MRID 49510306) for the inhalation toxicity study, giving as reasons that the formulation is packaged in small vials (containing from 0.23 mL to 4.0 mL of product; active ingredients are nonvolatile and application (directly to the skin of cats or dogs) does not result in respirable particles. A waiver for this study is appropriate with assignment to toxicity category IV.
5. After a comparison of the CSFs for 2517-RTA and 11556-125 it is concluded that the two formulations are toxicologically similar, so that the four cited studies (MRIDs 45096905, 45096907, 45096908 and 45096909) that were used to support 11556-125 will also support the registration of 2517-RTA.
6. An acute toxicity profile for 2517-RTA will be defined after an acceptable oral LD₅₀ study is submitted or cited.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: Venus Eagle, RM 01

Date: September 18, 2015

STUDY TYPE: Acute Oral Toxicity – Wistar rats Crl: WI (Han)
OPPTS 870.1100; OECD 425

TEST MATERIAL: CVSG 003; Lot No. #4.4; containing 96.92 mg/mL [8.84%] Imidacloprid and 4.84 mg/mL [0.441%] Pyriproxyfen. Described as a liquid with a density of 1.097 g/cm³.

SYNONYMS: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

CITATION: Allingham, P. (2014) Acute Oral Toxicity Up and Down Procedure with CVSG 003: Final Report. Project Number: 143382. Unpublished study prepared by BSL Bioservice Scientific Laboratories GmbH. 33p. MRID 49510307.

SPONSOR: ConVet GmbH & Co. KG
Alfred-Nobel Str. 10
40789 Monheim, Germany

SUBMITTER/DATA OWNER:
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710, USA

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 49510307), fasted (17-19 hrs) female Wistar rats (source: Charles River, Germany) were administered CVSG 003 at 2000 and 1500 mg/kg. For purposes of administration the test material was emulsified with vehicle (cottonseed oil); for 2000 mg/kg 1 g test material was emulsified to a final volume of 5 mL with dosage at 10 mL/kg body weight; for 1500 mg/kg 0.75 g test material was emulsified with vehicle to a final volume of 5 mL with dosage at 10 mL/kg body weight.

A single female (Animal no. 1) was dosed at 2000 mg/kg. This rat was euthanized at 1 hour and 40 minutes post-dose. Signs of toxicity included severe ataxia (2 minutes after dosage), comatose state (10 minutes after dosage), and comatose state and recumbency (lateral position) at 30 minutes and 1 hour.

From p. 20 of MRID 49510307: "One animal was dosed at the limit dosage of 2000 mg/kg body weight. As the animal died intercurrently, the new limit test was conducted to determine the LD₅₀. Five females were dosed at 1500 mg/kg body weight. As three animals survived the LD₅₀ was determined and no further testing was required." The two animals which died after dosage at 1500 mg/kg were sacrificed for ethical reasons, one at 33 minutes and one at 2 hours and 10 minutes after administration.

From information on page 11 of MRID 49510307 the first animal was dosed at 2000 mg/kg on July 31, 2014. Subsequent animals (numbers 2 through 6) were dosed at 1500 mg/kg, with individual rats dosed on August 7, 2014, August 12, 2014, August 19, 2014, August 28, 2014, and September 2, 2014.

The study is classified as supplementary, as there are a number of concerns regarding the conduct and results of this study. These include the following: 1) There is no mention (or guidance) for a limit dose of 1500 mg/kg in either the OECD or OCSPP (OPPTS) Guidelines; 2) For a limit dose at 2000 mg/kg the OECD guidance is: "Dose one animal at the test dose. If the animal dies, conduct the main test to determine the LD₅₀." 3) In the testing at 1500 mg/kg both the first and second animals died while the 9 sequences given on page 21 of MRID 49510307 all indicate survival of the first animal; and 4) Previous testing (MRID 45096904) of a toxicologically similar formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen gave LD₅₀ values of 1283 mg/kg for males (95% confidence limits were 680 to 1678 mg/kg) and 1000 mg/kg for females (95% confidence limits were incalculable).

Based on the considerations indicated above, we cannot accept an LD₅₀ > 1500 mg/kg from the results of this study, which should have defaulted to the up-and-down procedure after the death of the rat which was dosed at 2000 mg/kg.

RESULTS and DISCUSSION:

- A. **Mortality** – The one rat which was dosed at 2000 mg/kg was sacrificed for ethical reasons at 1 hour and 40 minutes after dosage. Two of the five rats dosed at 1500 mg/kg also were sacrificed for ethical reasons (one at 33 minutes and one at 2 hours and 10 minutes after dosage) and it is noted that these were the first and second rats dosed at 1500 mg/kg.
- B. **Clinical observations** – At 2000 mg/kg the one rat showed severe ataxia at 2 minutes post-dose, was comatose at 10 minutes, and was comatose and recumbent (lateral position) at 30 minutes and 1 hour. Effects seen at 1500 mg/kg included moderate to severe ataxia, abnormal rapid breathing, comatoseness, reduced spontaneous activity, moderately to severely reduced spontaneous activity, slight to moderate wasp waist, bradykinesia, half eyelid closure, with no signs of toxicity in survivors from day 5.
- C. **Gross Necropsy** – The three sacrificed animals (1 at 2000 mg/kg; two at 1500 mg/kg) had residues of the test item in their stomachs. There were no significant findings in the survivors.
- D. **Reviewer's Conclusions** – This study is classified as supplementary. This study should have defaulted to the up-and-down procedure (preferably with the first dose administered at 175 mg/kg) after the death of the rat which was dosed at 2000 mg/kg. It **does not** satisfy the guideline requirements for an acute oral toxicity study (OPPTS 870.1100; OECD 425) in the rat.

1. DP BARCODE: 427196				
2. PC CODES: 129099 (Imidacloprid); 129032 (Pyriproxyfen)				
3. CURRENT DATE: September 18, 2015				
4. TEST MATERIAL: CVSG 003; Sample ID E 179-14; Lot #4.4; a liquid with a density of 1.097 g/cm ³ ; containing 96.92 mg/mL (8.84%) Imidacloprid and 4.84 mg/mL (0.441%) Pyriproxyfen.				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity up-and-down (actually limit) test / rat / BSL Bioservice Scientific Laboratories GmbH, 82152 Planegg, Germany / Project No. 143382 / November 15, 2014 / OCSPP 870.1100; OECD 425	49510307	Female Wistar rats were used. One rat was dosed at 2000 mg/kg and died. Two of five rats dosed at 1500 mg/kg died. LD ₅₀ reported as greater than 1500 mg/kg; however, we cannot accept this finding as there is no mention (or guidance) for a limit dose of 1500 mg/kg in either the OECD or OCSPP (OPPTS) Guidelines and for a limit dose at 2000 mg/kg the OECD guidance is: "Dose one animal at the test dose. If the animal dies, conduct the main test to determine the LD50." In addition, previous testing (MRID 45096904) of a toxicologically similar formulation containing 9.1% Imidacloprid and 0.9% Pyriproxyfen gave LD ₅₀ values of 1283 mg/kg for males and 1000 mg/kg for females. All 3 deaths were sacrifices on the day of administration "for ethical reasons." Clinical findings at 1500 mg/kg included reduced spontaneous activity, ataxia, recumbency, comatose [state?], abnormal breathing, apathy, wasp waist, kyphosis, lethargy, bradykinesia, half eyelid closure, tremor, moving the bedding and piloerection. No signs of toxicity in survivors after day 5. Only necropsy finding was test item residues in stomachs of rats which were sacrificed.	-	S
Acute inhalation waiver request / Sergeant's Pet Care Products / Project Identification 11-14/06B / December 22, 2014 / OCSPP 870.1300; OECD 403	49510306	Product is packaged in small vials (from 0.23 mL to 4.0 mL); active ingredients are nonvolatile and application (to pets) does not result in respirable particles. Waiver is appropriate with assignment to toxicity category IV.	IV	W

Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DP BAR CODE NO.: 427195
PC Code: 129032,129099
FOOD Use: No

EPA File Symbol NO.: 2517-RTA
ACTION CODE: 315

DECISION NO.: 498900

DATE OUT: 08/26/ 2015

SUBJECT: End Use Product Chemistry Review
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze on for Dogs

FROM: Hari Mukhoty, DVM, PhD.
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Rita Kumar, RMR / Venus Eagle, RM 01
Invertebrate & vertebrate Branch 3/ Registration Division (7505P)

Company Name: Sergeant's Pet Care Products, Inc.
Formulation Type: Not Provided

INTRODUCTION:

The registrant has submitted a basic CSF (Dated: 03/02/2015), an amended CSF (Dated: 03/02/2015) as alternate formulation (Alt. # 1) for registration of the aforesaid products under EPA File Symbol No. 2517-RTA.

The product chemistry Group A and Group B data have been submitted under MRIDs: 495103-01 through -05.

The aforesaid basic end-use product and its Alt # 1 are manufactured by Sergeant's Pet Care Products, NE USA.

CITAB has been requested to evaluate the product chemistry data required for registration of the proposed formulations.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Imidacloprid (9.10%) and Pyriproxyfen (0.46%).
2. Has the registrant claimed substantial similarity to registered product?
[] Yes [X] No [] NA If yes: EPA Reg. No.
3. The source material of the active ingredient is registered with the Agency [Yes].
4. The CSF has been screened by inert group and they found that inerts are approved for non-food use.

DP BAR CODE NO.: 427195
PC Code: 129032,129099
FOOD Use: No

EPA File Symbol NO.: 2517-RTA
ACTION CODE: 315

DECISION NO.: 498900

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 03/02/2015 Re-submitted: NA
☒ Alternate - Alt #1 Dated: 03/02/2015 Re-submitted: NA

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐

6. Product label

a. Ingredient statement: Nominal concentrations of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☐ Yes ☐ No - Uses the term "Other Ingredients"

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"

, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid equivalent: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☒ No ☐ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 427195
PC Code: 129032,129099
FOOD Use: No

EPA File Symbol NO.: 2517-RTA
ACTION CODE: 315

DECISION NO.: 498900

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	495103-01
830.1600	Description of materials used to produce the product			"	A	"
830.1650	Description of formulation process			"	A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			NR	NR	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	See CSFs dated 02/ 03/ 2015 / CLs are standard
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method #		X		A	495103-02

A = Acceptance, NR = Not Required, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Acceptable

Analytical Method: HPLC method using UV detector set at Wave length: 270 nm. Validation data have been submitted.

DP BAR CODE NO.: 427195
PC Code: 129032,129099
FOOD Use: No

EPA File Symbol NO.: 2517-RTA
ACTION CODE: 315

DECISION NO.: 498900

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	495103-03, -04
830.6314	Oxidation/reduction	Not Oxidizer or Reducer.	A	"
830.6315	Flammability	208 °F.	A	"
830.6316	Explodability	Not potentially explosive	A	"
830.6317	Storage stability	Product was stable for 14 days at 54°C,	A	495103-03 & -05
830.6310	Miscibility	NA / not to be diluted with water / petroleum solvent is not to be used	A	"
830.6320	Corrosion characteristics	No signs of corrosion at 54° C in 14 Days.	A	495103-03 & -05
830.7000	pH	Not to be mixed or dispersed in water. Consequently, there is no hydrogen ion concentration to be measured for pH.	A	495103-03
830.7100	Viscosity	6.77 mPas @ 20° C	A	"
830.7300	Density	1.097 g/cm ³	A	"
830.7520	Particle size	NA / Product is liquid.	NA	"

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

DP BAR CODE NO.: 427195
PC Code: 129032,129099
FOOD Use: No

EPA File Symbol NO.: 2517-RTA
ACTION CODE: 315

DECISION NO.: 498900

CONCLUSIONS:

1. CITAB has reviewed the CSFs (Dated: 03/02/2015) for the proposed basic and alternate formulation (Alt. # 1) and finds those to be acceptable. The CSFs are attached with this review and can be located in OPPIN CHEM DOCS.
2. Product chemistry Group A data, and Group B data are satisfied and acceptable.
3. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

July 23, 2015

MEMORANDUM

Subject: Name of Pesticide Product: SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN
SQUEEZE-ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTA
DP Barcode: DP 427197
Decision No.: 498900
Action Code: R315
E-Sub#: --
PC Codes: 129099 (Imidacloprid: 9.1%)
129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

To: Rita Kumar/Venus Eagle
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

Byron T. Backus
July - 23 - 2015
JCR

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
Other Ingredient(s):	90.44%
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"...Please provide a...full review of cited data to support registration of this me-too new registration application for a dog pour-on [note: proposed product is packaged in 0.4, 1.0, 2.5 and 4.0 mL vials,

and the use directions indicate it is a spot-on, rather than a pour-on] product. This is an e-submission, and all the information is in Documentum – data matrix, cover letter, data. Copies of cover letter, proposed label, and CSFs are enclosed. Please use this hard copy of the label and CSFs which are more current copies and will be uploaded to Documentum in due course...”

BACKGROUND: From the proposed label for EPA Reg. No. 2517-RTA, doses are 0.4 mL (0.014 fl. oz.) for dogs weighing 3 to 10 lbs, 1.0 mL (0.034 fl. oz.) for dogs weighing 11-20 lbs, 2.5 mL (0.085 fl. oz.) for dogs weighing 21-55 lbs, and 4.0 mL (0.135 fl. oz.) for dogs weighing more than 55 lbs.

According to the data matrix (dated December 23, 2014) for EPA File Symbol 2517-RTA the registrant has cited the following studies to satisfy the companion animal safety data requirements for this product: MRIDs 43679607, 43679608, 44099801, 44179801, 45097101, and 45097102.

PREVIOUS REVIEWS:

1. The study in MRID 43679607 was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

Nine adult dogs of mixed breed (3 males, 6 females, one male and two females/group) were dermally exposed to Imidacloprid, 10% Spot-On. Dose levels were 50 mg/kg/day x 1 day, and 50 mg/kg/day x 3 days. Controls received placebo (formulation less active ingredient) at 50 mg/kg/day x 3 days.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg without significant reactions.

This...study is classified as Acceptable when combined with another study, and satisfies the requirement for a domestic animal study in the dog, 18 lb (8 kg) body weight and above. The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the dog (MRID 43679608), the information is considered useful.

2. The study in MRID 43679608 was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

18 adult dogs of various breeds (3 males and 3 females/group) were dermally exposed to Imidacloprid, 10% Spot-On formulation at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50 mg/kg.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg of the active ingredient without significant reactions. Inadequate testing was done in dogs less than four months old.

This repeated dose dermal study is classified as Acceptable and satisfies the requirements for a General Safety Evaluation for Topical Use (96-1) in the dog.

3. The study in MRID 44099801 was reviewed in HED (TXR 0012322, sign-off date 09/24/97) with the following summary:

In a domestic animal safety study (MRID #44099801), six 7 week-old puppies/sex were treated with AdvantageTM (9.1% imidacloprid) at 5X the recommended use rate (2.0 mL if < 10 lbs; 5.0 mL if > 10 lbs) at weekly intervals for eight treatments. Six puppies/sex were treated with the vehicle control at the recommended use rate (0.4 mL if < 10 lbs; 1.0 mL if > 10 lbs) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 7 week-old puppies can tolerate a dose of 5X the recommended use rate.

The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.

4. There is no record of a review for the study in MRID 44179801 [Shmidl, J.; Arther, R. (1996) Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.]. The following is a summary of that study:

The study was conducted to evaluate the acute toxicity of the formulation and the formulation minus the active ingredient (placebo) when administered orally at the topical use rate. The labeled use rate is 1.0 mL for dogs weighing 11 to 20 lb; 2.5 mL for 21 to 55 lb and 5.0 mL for dogs weighing > 55 lb. Group 1 dogs received a single treatment of placebo (formulation minus the active ingredient) equivalent to use rate volume. Group 2 dogs received a single treatment of the formulation at the use rate volume.

The treatment volumes were placed in gelatin capsules and administered directly in the throat area. The gelatin capsules were swallowed intact.

Two dogs in Group 2 vomited at approximately one hour following treatment. None of the remaining 10 dogs had any clinical signs.

The purpose and protocol of this study are inconsistent with the 870.7200 Guidelines. This study, while providing relevant information, does not satisfy the 870.7200 data requirements.

5. The following is taken from the executive summary from the review (TXR 5001580, dated September 8, 2000) of the study in MRID 45097101 (beagle puppies, 7 weeks old at the time of the first treatment):

In a companion animal safety study (MRID 45097101), Advantage Plus[®] for Dogs (active ingredients: 9.1% Imidacloprid w/w; 0.9% Pyriproxyfen w/w) was applied topically at a dose of 2.0 mL/puppy (5X the label specified dose of 0.4 mL/puppy for puppies ≤ 10 lbs) to a group of 7 male and 7 female beagle puppies, seven weeks of age at the time of first treatment. Individual weights of the puppies in the treatment group ranged from 2.54 to 4.01 lbs (1.15-1.82 kg) on day

-1. Controls (7M, 7F; weight range 2.49-5.03 lbs; 1.13-2.29 kg) were dosed with the vehicle alone at a dose of 2.0 mL/puppy (5.6X the volume of the vehicle present in the specified dose). Both groups were treated on study days 0, 7, 14, and 21. The recommended label dose is once a month. However, the labeling for these products includes the statement: "If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly."

There were no deaths during the study. Following all treatments, a rough hair coat condition at the application site was noted on 3-14 puppies of both groups, and white powder was occasionally noted at the application sites; however, there were no signs of irritation...

Despite the fact that the puppies may not have been entirely free of infection, and despite some deficiencies in the reporting of the data, the study is classified as **Acceptable** as a companion animal safety study (OPPTS 870.7200) in puppies. The lack of any indications of a consistent toxicological response following exposures (a total of 4) to 5X label-specified use applications of the test material indicates that an adequate safety margin exists for this formulation and its proposed use on puppies 7 weeks of age and older.

6. The following is taken from the executive summary from the review (TXR 5001580, dated September 8, 2000) of the study in MRID 45097102 (adult dogs):

In a companion animal safety study (MRID 45097102) with adult beagles (ages ranging from 1 year and 3 months to 6 years), Advantage Plus® for Dogs (active ingredients: 9.1% Imidacloprid w/w; 0.9% Pyriproxyfen w/w) was applied topically at dose volumes of 5.0 mL for dogs weighing 11-20.4 lbs and 12.5 mL for dogs weighing 20.5-55 lbs (five times the recommended dose) to groups of 6 male and 6 female dogs... Controls were dosed with the vehicle at dose volumes of 5.0 mL for dogs weighing 11-20.4 lbs and 12.5 mL for dogs weighing 20.5-55 lbs (5.6 times the volume of the vehicle in the recommended dose)... Dogs were treated on study days 0, 7, 14, and 21.

There were no deaths during the study. The dogs received no concomitant medication or therapy during the treatment period. The most prominent clinical sign was a rough appearance of the hair coats on dogs from both groups following treatment and lasting for up to 36 hours; however, there were no signs of irritation...

The study is classified as **Acceptable/Guideline** as a companion animal safety study (OPPTS 870.7200) in dogs. The lack of any consistent indications of a toxicological response following exposures (a total of 4) to 5X label-specified use applications of the test material indicates that an adequate safety margin exists for this formulation and its proposed use on adult dogs.

7. In a TRB memorandum ("Minimum Treatment Weight and Age for EPA Reg. No. 11556-128") dated October 12, 2012 it was stated that:

"From data on pages 30 and 32 of MRID 45097101, the mean weight of the 7 males was 3.44 ± 0.39 lbs, while the mean weight of the 7 females was 3.06 ± 0.45 lbs. However, the 870.7200 Guidelines specify 6 animals/sex, so if the heaviest male and female are excluded, then the mean weight of the remaining 6 males was 3.34 ± 0.32 lbs, while the mean weight of the remaining 6 females was 2.92 ± 0.28 lbs (the mean weight of these 6 males and 6 females was 3.13 ± 0.36 lbs). **Based on these considerations, we can accept 3 lbs as the lowest minimum weight.**"

“Individual puppy ages are reported on page 27 of MRID 45097101. The ages of the puppies on the day of first dosing ranged from 6 weeks and 5 days to 7 weeks and 0 days. **We can accept 7 weeks as the minimum age.**”

COMMENTS AND RECOMMENDATIONS:

1. After comparing the CSFs for 2517-RTA and 11556-125, 11556-127, 11556-128 and 11556-130, CITAB concludes that these formulations are substantially similar, and that the companion animal safety studies that supported the registration of 11556-125 (and -127, -128, and -130) also support the registration of 2517-RTA.
2. Based on the TRB reviews dated September 8, 2000 for 11556-125 and October 12, 2012 for 11556-128, CITAB concludes that the companion animal safety studies in MRIDs 45097101 and 45097102 (cited in the data matrix dated December 23, 2014) satisfy the 870.7200 data requirements to support the registration of 2517-RTA for use on adult dogs and puppies 7 weeks of age and older, and support 3 pounds as the minimum weight (associated with a dose of 0.4 mL). The proposed doses and associated weight ranges [0.4 mL (0.014 fl. oz.) for dogs weighing 3 to 10 lbs, 1.0 mL (0.034 fl. oz.) for dogs weighing 11-20 lbs, 2.5 mL (0.085 fl. oz.) for dogs weighing 21-55 lbs, and 4.0 mL (0.135 fl. oz.) for dogs weighing more than 55 lbs] are acceptable.

Kumar, Rita

From: Marchese, Jacquelyn
Sent: Wednesday, May 27, 2015 8:27 AM
To: Kumar, Rita
Subject: 2517-RTA, 2517-RTL Pass Technical Screens

Hi Rita,

2517-RTA and 2517-RTL pass the technical screens. Per my previous email, once you get me the densities for 2517-RTU and 2517-RTG I can take a look at those packages too.

Thanks,
Jackie

Jacquelyn Marchese
Entomologist
OCSPP/OPP/RD/IVB3
Email: Marchese.Jacquelyn@epa.gov
Phone: (703) 347-0559

Kumar, Rita

From: Hashim, Masih
Sent: Friday, May 15, 2015 11:40 AM
To: Kumar, Rita; Rudick, Maggie
Subject: 2517-RLA 2517-RTL 279-GUTT
RTT ?

The subjects actions have passed the screening process. T
This note is FYI



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D427195; **FILE SYMBOL No.:** 2517-RTA (screen); **PRODUCT NAME:** Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs; **DECISION No.:** 498900; **PC Code(s):** 129099, 129032; **ACTION CODE:** R315; **FOOD Use:** No

DATE OUT: May 14, 2015

SUBJECT: Completeness check screening for end use product "Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB / RD (7505P)

TO: Rita Kumar / Venus Eagle, RM 01
I-V Branch 3 / RD (7505P)

Company Name: Sergeant's Pet care products Incorporation
Formulation Type: Insecticide
Active Ingredient(s): Imidacloprid (9.1%); Pyriproxyfen (0.46%)
MRID No(s): 49510301 to 49510305

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

Group A: All required data submitted

Group B: All required data submitted

CSF: Basic & alternate CSF #1 (dated 03-02-2015) has been submitted

Product label: Yes

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 11, 2015

MEMORANDUM:

Subject: Name of Pesticide Product: SERGEANT'S IMIDACLOPRID + PYRIPROXYFEN
SQUEEZE ON FOR DOGS
EPA Reg. No. /File Symbol: 2517-RTA
DP Barcode: DP 427197 (screening review)
Decision No.: 498900
Action Code: R315
PC Codes: 129099 (Imidacloprid: 9.10%)
129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
IVB1
Registration Division (7505P)

Byron T. Backus
May 11, 2015
Angela McChesley

To: Rita Kumar RM 01
IVB3
Registration Division (7505P)

Registrant: SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
<u>Other Ingredients:</u>	90.44%
TOTAL	100.00%

ACTION REQUESTED: "...Please provide a technical screen and full review of cited data to support registration of this me-too new registration application for a dog pour-on product..."

COMMENTS AND RECOMMENDATIONS:

1. The registrant is citing MRIDs 43679607, 43679608, 44099801, 44179801, 45097101 and 45097102 to satisfy the companion animal (dog and puppy) safety study data requirements for the registration of 2517-RTA.
2. After a search in OPPIN query, it is concluded that these citations are sufficient to allow a full review to determine whether the companion animal safety data requirements for the registration of 2517-RTA have been satisfied and if the proposed dosages, minimum age and minimum weight are supported.

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Thursday, May 07, 2015 11:51 AM
To: Kumar, Rita
Subject: FW: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-

Hi, Rita,

I want to make sure I understand next actions. I do not want to be responsible for holding up any further review. I have not yet submitted the labels and revised CSFs to the front end as I was not certain if the Agency prefers hard copies or a new CD with all documents – the revised CSFs and the other initially e-submitted documents.

Please let me know.
Thank you,
Mary

CD w/ a hard copy letter explaining what's in the CD.

From: Mary Hunt
Sent: Tuesday, May 05, 2015 6:23 PM
To: 'Kumar, Rita'
Cc: James Messina; Eagle, Venus
Subject: RE: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-

Hi, Rita,

I'm hoping for some clarification on bullet point #2. At first I thought you would like hard copies of the labels and CSFs submitted through the front end, but I'm thinking I might have misunderstood. Does the Agency prefer a CD with all documents submitted initially and the revised versions of documents (CSFs, labels) be sent instead of hard copies? Please let me know.

"You submitted revised labels and CSFs for both of these products (RTL and RTA) on 3/2/2015 via e-mail. Please send these revised versions thru front end also, so that Documentum can be updated accordingly for the e-submission of these applications. In future, you must make sure that any changes in the e-submission must be done thru front end, so that Documentum can be updated in a timely fashion."

Thank you,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Tuesday, May 05, 2015 12:25 PM
To: Mary Hunt
Cc: James Messina; Eagle, Venus
Subject: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-

Hi Mary: I hope you are doing well. Please address the following re these applications:

1. I need new formulator's exemption forms for 2517-RTA and 2517-RTL. One dated 3/2/2015 does not list all the alternate sources of pyriproxyfen that are mentioned in the alt csf 1.
2. You submitted revised labels and CSFs for both of these products (RTL and RTA) on 3/2/2015 via e-mail. Please send these revised versions thru front end also, so that Documentum can be updated accordingly for the e-

submission of these applications. In future, you must make sure that any changes in the e-submission must be done thru front end, so that Documentum can be updated in a timely fashion.

3. Also confirm that the basic and alternate 1 CSFs are the only CSFs for these two applications, and the previously submitted versions are obsolete or withdrawn by you.
4. New data citation forms are needed for three products, 2517-RTG, 2517-RTU, and 2517-RTL, because the offer-to-pay box is not checked in this form for these products.

Regards,
Rita

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, May 05, 2015 4:10 PM
To: Kumar, Rita
Subject: FW: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-
Attachments: 2517-RTL Form Ex 8570-27_RevFont.pdf; 2517-RTA Form Ex 8570-27_RevFontSize.pdf

From: Mary Hunt
Sent: Tuesday, May 05, 2015 3:56 PM
To: 'Kumar, Rita'
Cc: James Messina; Eagle, Venus
Subject: RE: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-

Hi, Rita,

Thank you for your email. Please see my comments below in blue.

Rita, after you review the comments, please let me know if you have any questions or need further information.

Thank you,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Tuesday, May 05, 2015 12:25 PM
To: Mary Hunt
Cc: James Messina; Eagle, Venus
Subject: Sergeant's Pending imidacloprid Pet spot -on applications for cats and dogs - 2517-

Hi Mary: I hope you are doing well. Please address the following re these applications:

1. I need new formulator's exemption forms for 2517-RTA and 2517-RTL. One dated 3/2/2015 does not list all the alternate sources of pyriproxyfen that are mentioned in the alt csf 1. The pyriproxyfen sources were all listed on the pdfs, but unfortunately one must scroll down to see each one. We were able to reduce the font size on that form, so that all sources can now be seen. Please see attached Formulator's exemption forms for 2517-RTA and 2517-RTL.
2. You submitted revised labels and CSFs for both of these products (RTL and RTA) on 3/2/2015 via e-mail. Please send these revised versions thru front end also, so that Documentum can be updated accordingly for the e-submission of these applications. In future, you must make sure that any changes in the e-submission must be done thru front end, so that Documentum can be updated in a timely fashion. The revised labels and CSFs for the 2517-RTA and 2517-RTL were emailed to Shaunta Hill per her directions, and I did not think to send also through Front End. Thank you for the info. Hard copies will be delivered to the Front End tomorrow.
3. Also confirm that the basic and alternate 1 CSFs are the only CSFs for these two applications, and the previously submitted versions are obsolete or withdrawn by you.

The Basic CSF and Alternate Source CSF #1 dated 3/02/2015 are correct for 2517-RTL and 2517-RTA. They replace all of the initially submitted CSFs dated 12/22/2014.

4. New data citation forms are needed for three products, 2517-RTG, 2517-RTU, and 2517-RTL, because the offer-to-pay box is not checked in this form for these products.

Please let me know if I have misunderstood the requirements: Since there was no "cite-all" listed for any guideline data requirement on the data matrices for these products, and offer to pay compensation letters were sent to the selective citation data owners, it is my understanding that the general offer to pay box is not checked under these circumstances. Please advise.

Regards,
Rita

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 28, 2015 3:38 PM
To: Kumar, Rita
Subject: RE: Sergeant's pet product applications
Attachments: Transmittal for Dog Imid + PPF Submission.pdf

Hi, Rita,

I've figured it out! Please see below, and do not hesitate to call me if you have any questions or need further clarification.

For Imidacloprid-only containing products 2517-RTU (dog) and 2517-RTG (cat):

New Sergeant's Product Chemistry data was submitted under 2517-RTU (transmittal doc emailed earlier today), and that same new data is cited for 2517-RTG to support its product chemistry. The companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. No CRP data is required as the acute toxicity did not trigger CRP testing/packaging.

For the imidacloprid/pyriproxyfen containing products, 2517-RTA (dog) and 2517-RTL (cat):

Again, new Sergeant's Product Chemistry was submitted under 2517-RTA (transmittal attached), and the same product chemistry data was cited to support the cat application, 2517-RTL. Also, a new acute inhalation toxicity waiver request and a new acute oral toxicity study have been submitted under 2517-RTA, and the same toxicity data was cited to support the cat application, 2517-RTL. Note that the companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. Again, the requirement for CRP testing/packaging was not triggered by the acute toxicity data.

I hope this is helpful. Again, please just give me a call if you have further questions.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, April 28, 2015 12:16 PM
To: Mary Hunt
Subject: RE: Sergeant's pet product applications

Thanks, Mary. So, this product chemistry data is to support all four registrations? Also, am I correct in assuming that all other data were cited? In the data matrix, I find only acute toxicity and efficacy data citations, but nothing for companion animal or CRP. Can you please clarify. Thanks.

Rita

From: Mary Hunt [mailto:mhunt@exponent.com]
Sent: Tuesday, April 28, 2015 11:58 AM

To: Kumar, Rita
Cc: Kelly Hoskins; Eagle, Venus; Stephanie Sarraïno
Subject: RE: Sergeant's pet product applications

Hi, Rita,

Thank you for the email. I don't know if it is helpful to you, but these were submitted electronically, and my understanding was that a transmittal was submitted. That being said, please see the attached transmittal and note that all data was submitted under the 2517-RTU imidacloprid dog spot on. Please let me know if you need any other information or further clarification.

Thanks, again,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Tuesday, April 28, 2015 11:46 AM
To: Mary Hunt
Cc: Kelly Hoskins; Eagle, Venus
Subject: Sergeant's pet product applications
Importance: High

Hi Mary: I am doing a preliminary review of these applications. I noticed that there is no transmittal document. Can you please clarify what new data you are submitting to support these four cat and dog products, esp. what is being done for product chemistry. A transmittal document is helpful for us to know what new data are submitted, and we can assume that rest of the data in data matrix are cited.

Regards,
Rita

Kumar, Rita

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, April 28, 2015 3:38 PM
To: Kumar, Rita
Subject: RE: Sergeant's pet product applications
Attachments: Transmittal for Dog Imid + PPF Submission.pdf

Hi, Rita,

I've figured it out! Please see below, and do not hesitate to call me if you have any questions or need further clarification.

For Imidacloprid-only containing products 2517-RTU (dog) and 2517-RTG (cat):

New Sergeant's Product Chemistry data was submitted under 2517-RTU (transmittal doc emailed earlier today), and that same new data is cited for 2517-RTG to support its product chemistry. The companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. No CRP data is required as the acute toxicity did not trigger CRP testing/packaging.

For the imidacloprid/pyriproxyfen containing products, 2517-RTA (dog) and 2517-RTL (cat):

Again, new Sergeant's Product Chemistry was submitted under 2517-RTA (transmittal attached), and the same product chemistry data was cited to support the cat application, 2517-RTL. Also, a new acute inhalation toxicity waiver request and a new acute oral toxicity study have been submitted under 2517-RTA, and the same toxicity data was cited to support the cat application, 2517-RTL. Note that the companion animal safety studies are listed for each product under Toxicology Requirements, Guideline 870.7200, in the respective data matrices. Again, the requirement for CRP testing/packaging was not triggered by the acute toxicity data.

I hope this is helpful. Again, please just give me a call if you have further questions.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Tuesday, April 28, 2015 12:16 PM
To: Mary Hunt
Subject: RE: Sergeant's pet product applications

Thanks, Mary. So, this product chemistry data is to support all four registrations? Also, am I correct in assuming that all other data were cited? In the data matrix, I find only acute toxicity and efficacy data citations, but nothing for companion animal or CRP. Can you please clarify. Thanks.

Rita

From: Mary Hunt [mailto:mhunt@exponent.com]
Sent: Tuesday, April 28, 2015 11:58 AM

To: Kumar, Rita
Cc: Kelly Hoskins; Eagle, Venus; Stephanie Sarraïno
Subject: RE: Sergeant's pet product applications

Hi, Rita,

Thank you for the email. I don't know if it is helpful to you, but these were submitted electronically, and my understanding was that a transmittal was submitted. That being said, please see the attached transmittal and note that all data was submitted under the 2517-RTU imidacloprid dog spot on. Please let me know if you need any other information or further clarification.

Thanks, again,
Mary

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Tuesday, April 28, 2015 11:46 AM
To: Mary Hunt
Cc: Kelly Hoskins; Eagle, Venus
Subject: Sergeant's pet product applications
Importance: High

Hi Mary: I am doing a preliminary review of these applications. I noticed that there is no transmittal document. Can you please clarify what new data you are submitting to support these four cat and dog products, esp. what is being done for product chemistry. A transmittal document is helpful for us to know what new data are submitted, and we can assume that rest of the data in data matrix are cited.

Regards,
Rita



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138-3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

April 20, 2015

Venus Eagle, PM 1
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Eagle:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517), authorizes Exponent, Inc. (1150 Connecticut Avenue, NW, Suite 1100, Washington DC, 20036) to act on our behalf, as an Authorized Representative, for all necessary interactions regarding our product registration applications and registrations. Please note that this does not change the current filed Authorized Agent for Sergeant's Pet Care Products, Inc.

The Exponent, Inc. contacts include as follows:

Jim Messina and/or Mary M. Hunt and/or Reg Coler
Exponent, Inc.
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036
(202) 772-4932 / (202) 549-9761 / (202) 772-4965
(202) 772-4979 fax
jmessina@exponent.com / mhunt@exponent.com / rcoler@exponent.com

If you have any questions, please contact me at (402) 938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

cc: Jim Messina, Exponent, Inc.

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Tuesday, March 03, 2015 1:15 PM
To: Hill, Shaunta
Subject: pending EPA Reg. No. 2517-RTA
Attachments: 2517-RTA Revised Label 3-02-15.pdf; 2517-RTA Cert-Data 8570-34.pdf; 2517-RTA Basic CSF Imidacloprid + PPF Dog 3-2-15.pdf; 2517-RTA Alt CSF #1 Imidacloprid + PPF Dog 3-02-15.pdf; 2517-RTA Form Ex 8570-27.pdf

Hi, Shaunta,

Per our discussions regarding the pending application for new pesticide product, please see the attached revised documents for Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs. I understand that you will forward these documents to the PM, Venus Eagle.

You may recall, this action was required by the Agency to be changed from a PRIA3 category R310 to category R315.

Note that the Master label has been revised to reduce [brackets] in efficacy claims to make the statements clearer. Per the Agency's request, a revised EPA form 8570-34 Certification with Respect to Citation of Data is attached; please be aware that offer to pay compensation letters were sent to the selective citation data owners.

Also, please switch/exchange the previously submitted initial Confidential Statements of Formula with the attached Basic CSF and Alternate Source Formulation #1 CSF – both dated 3/02/2015; a new EPA form 8570-27 Formulator's Exemption is attached.

Please do not hesitate to call me if you have any questions or need further clarification.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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Rec'd 3/24/15



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-RTA
	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dog⁺
	Date of Confidential Statement of Formula (EPA Form 8570-4) 3/02/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Imidacloprid, Pyriproxyfen

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid		
Imidacloprid		
Imidacloprid		
Imidacloprid		
Pyriproxyfen		
Pyriproxyfen		
Pyriproxyfen		
Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date 3/02/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Hill, Shaunta

From: Mary Hunt <mhunt@exponent.com>
Sent: Friday, February 13, 2015 3:39 PM
To: Hill, Shaunta
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Hi, Shaunta,

FYI....

Thank you,
Mary

-----Original Message-----

From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Friday, February 13, 2015 2:03 PM
To: Prince Bamaze
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25JPP3K6
Agency Tracking ID: 74752774031

Account Holder Name: Sergeants Pet Care Products Inc
Transaction Type: ACH Debit
Transaction Amount: \$19,892.00
Payment Date: 02/17/2015
Account Type: Business Checking
Routing Number: 121100782
Account Number: *****0100

Transaction Date: 02/13/2015 03:02:50 PM EST
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number: 2517-RTG; -RTU;-RTL;-RTA
Company Name: SERGEANT'S
Company Number: 2517
Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

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if this e-mail message contains a forwarded message or is a reply to a prior message, some or all of the contents of this message or any attachments may not have been produced by the sender. This notice is automatically appended to each e-mail message leaving the senders e-mail domain. Thank you.

Hill, Shaunta

From: Hill, Shaunta
Sent: Wednesday, February 11, 2015 2:20 PM
To: Yanchulis, Michael
Cc: Eagle, Venus; Schaible, Stephen
Subject: Recode request

Hello Mick,

Could you please recode the following applications to **R315s** and bill the registrant for the balance of the PRIA fee? If at all possible, notice of the total amount due for all of the applications would be appreciated. Provided below is the company's agreement to the recode.

If you have any questions, please let me know.

EPA File Symbol

2517-RTG, decision 498685

2517-RTU, decision 498903

2517-RTL, decision 498686

2517-RTA, decision 498900

Regards,

Shaunta Hill, Ph. D.

Acting RD PRIA Ombudsman

U.S. EPA: Office of Chemical Safety and Pollution Prevention

Registration Division

1200 Pennsylvania Avenue, NW (7505P)

Washington, DC 20460

Tel: 703.347.8961 1 Fax: 703.305.6920

E-mail: hill.shaunta@epa.gov

URL Address: www.epa.gov/pesticides

From: Mary Hunt [mailto:mhunt@exponent.com]

Sent: Wednesday, February 11, 2015 1:32 PM

To: Hill, Shaunta

Subject: Sergeant's pending recode

Hi, Shaunta,

On behalf of our client, Sergeant's Pet Care Products, Inc., please move forward to recode to PRIA3 R315 the following pending applications:

EPA File Symbol

2517-RTG

2517-RTU

2517-RTL
2517-RTA

Please combine the 4 recode letters into one letter with a total amount due, if possible. This may be more efficient for both the Agency and Sergeant's.

Finally, please let me know how we might expedite the review period since the "fee for service dates" and "PRIA clock" were stalled and will be restarted.

Thank you,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

Exponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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Memorandum

Date: 01 / 14 / 2015

To: PM 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Waiting for date
AB 1/16/15

21-Day Screen Completed by
Contractor

21-Day Expires on 1-13-15

Jacket # 2517-RTA
MRID# 495103

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAUCE

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12/23/14

Experts In-Processing Signature: WAP

Date 1/9/15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2517-RTA</u>		EPA Receipt Date: <u>12/23/14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			Y		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Inerts approved for non-food use

* submitted studies Passed PRN 11-3 Review

* Tactel Passed

JJ 1/15/15

MRID: 495103

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis	X					
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X					
830.6316	Explodability	X					
830.6317	Storage stability	X					
830.6319	Miscibility	X					
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage	X					
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)	X			
870.1300	Acute Inhalation (LC50)	X			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	X			
870.2600	Dermal Sensitization	X			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					not required
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					↓
810.3300	Treatments to Control Pests of Humans and Pets	X				
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					not required
810.3500	Premises Treatments					↓
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					↓

-----Original Message-----

From: pay.gov.clev@clev.frb.org [<mailto:pay.gov.clev@clev.frb.org>]

Sent: Friday, January 09, 2015 11:02 AM

To: Prince Bamaze

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or by email at yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25J89JSO

Agency Tracking ID: 74734454203

Account Holder Name: Sergeants Pet Care Products Inc

Transaction Type: ACH Debit

Transaction Amount: \$2,479.00

Payment Date: 01/12/2015

Account Type: Business Checking

Routing Number: 121100782

Account Number: *****0100

Transaction Date: 01/09/2015 12:01:35 PM EST

Total Payments Scheduled: 1

Frequency: OneTime

Registration Number: 2517-NEW

Company Name: SERGEANT'S

Company Number: 2517

Action Code: R310

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 9, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-498900
EPA File Symbol or Registration Number: 2517-RTA
Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs
EPA Receipt Date: 23-Dec-2014
EPA Company Number: 2517
Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310
NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED
SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO
OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER
REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD
ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY;CHILD
RESISTANT PACKAGING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m/jk", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Yanchulis, Michael

From: Yanchulis, Michael
Sent: Wednesday, December 31, 2014 3:06 PM
To: 'khoskins@sergeants.com'
Subject: 4 Pesticide Applications

Dear Kelly,

I have been working on putting the payments together as you laid out in your letters for the 4 new pesticide applications, but I have one big roadblock. Payment ID 25EJD841 in the amount of \$3,798 was used to pay for an amendment to Reg. No. 2517-63 in August. Here is the payment status of your applications:

- Sergeant's 9.1% Imidacloprid Spot On for Cats (Symbol No. 2517-RTG): I was able to fund as you prescribed.
- Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats (Symbol No. 2517-RTL): I was able to use \$3,798 from 25EJDG2F as you prescribed but could not use the \$650 from 25EJD841 so I used \$605 from 25CH12VE (now exhausted) and \$45 from 25DRV902 so this one is paid in full.
- Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs (Symbol No. 2517-RTA): I could not process because of the unavailability of funds under 25EJD841. I have the following funds still available for a total of \$2,569 (\$950 from 25DRV51S; \$950 still left from 25DRV3K1; \$488 still left from 25DRV902; and \$181 from 25CTS3PH) leaving \$2,479 still due. Please send me a pay.gov receipt for this amount.
- Sergeant's 9.1% Imidacloprid Squeeze On for Dogs (Symbol No. 2517-RTU): I could not find a copy of the pay.gov in the amount of \$1,806 for the R301 action code so please send me the receipt or tracking ID.

So in summation, I was able to process and move forward the two cat applications but not the two dog applications.

*Mick Yanchulis
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency*

Fee for Service

79
{962169G~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S-

962169

EPA File Symbol/Reg. No.

2517-RTA

Pin-Punch Date:

12/23/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 5,048.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Roe

Date: 12/30/14

Remarks:

sim clinic

e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 29, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SERGEANT'S PET CARE PRODUCTS, INC.
PO.BOX : 540399
OMAHA, NE 68154-0399

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 23-DEC-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new end-use product, Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs.

SUBMITTAL DATE:

December 23, 2014

Volume	Study Title	MRID No.
1	Administrative Materials	49510300
2	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301
3	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302
4	Summary of Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303
5	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304
6	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305
7	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306
8	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-NEW
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 12/23/2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Kelly R. Hoskins</i>	Date 12/23/2014	Typed or Printed Name and Title Kelly R. Hoskins, Director of Regulatory Affairs
--------------------------------------	--------------------	---

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

CONTACT PERSON (Return to)

James Messina
Exponent, Inc.
1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support an EPA registration application for the new end-use product, Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs.

SUBMITTAL DATE:

December 23, 2014

Volume	Study Title	MRID No.
1	Administrative Materials	49510300
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8	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307

Receipt for Section 3

S: 962169

Milestone Email: khoskins@sergeants.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 1

Product #: 2517-RTA Product Name: Sergeant's Imidacloprid + Pyriproxyfen Squee

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 23-Dec-2014



OPP Rec'd Date: 23-Dec-2014



Front End Date: 24-Dec-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Associated with e-Submission pkg 7042. Application for new use product on Dogs

New Ingredient

Request Date:

New ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

e-Submission

EPAUnited States
Environmental Protection Agency

Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-NEW	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc./Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs	5. PM #1	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. Nos. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Sergeant's Pet Care Products, Inc. is submitting a registration application for a new end-use product containing Imidacloprid (9.1%) and Pyriproxyfen (0.46%) for dogs. Sergeant's requests that the Agency review the end-use product registration as a 7 month PRIA timeframe under R310.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted			
If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)		No. per Container 1, 2, 3, 4, 5, 6, 12, 24, 50, 75, 100 vials	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various (see above)	5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Printed box <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James B. Messina	Title Authorized Representative	Telephone No. (Include Area Code) (202) 772-4932
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>	3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins	5. Date: December 23, 2014	

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

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James Messina
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1150 Connecticut Ave. NW, Suite 1100
Washington, DC 20036

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SUBMITTAL DATE:

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e-Submission



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710	EPA File Symbol/Registration Number 2517-NEW
	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dog+
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/23/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Imidacloprid, Pyriproxyfen

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid		
Imidacloprid		
Imidacloprid		
Imidacloprid		
Pyriproxyfen		
Pyriproxyfen		
Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date 12/23/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	EPA Registration Number/File Symbol 2517-NEW
Active Ingredient(s) and/or representative test compound(s) Imidacloprid, Pyriproxyfen	Date 12/23/2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor non-food	Product Name Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

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I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Kelly R. Hoskins

Date

12/23/2014

Typed or Printed Name and Title

Kelly R. Hoskins, Director of Regulatory Affairs



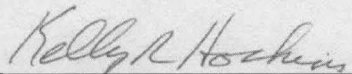
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 23, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 1 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750	Group A Product Chemistry for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510301	Sergeant's Pet Care Products	OWN	
830.1800	Analytical Method for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510302	Sergeant's Pet Care Products	OWN	
830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Group B Product Chemistry and Waivers for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510303	Sergeant's Pet Care Products	OWN	
830.6302, 830.7100, 830.7300	Physical and Chemical Characteristics: Color, Viscosity, and Density for Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510304	Sergeant's Pet Care Products	OWN	
830.6317, 830.6320	Accelerated 14-Day Storage Stability and Corrosion Characteristics of Sergeant's Imidacloprid + Pyriproxyfen Spot On Products	49510305	Sergeant's Pet Care Products	OWN	
830.6315	Flashpoint for Sergeant's 9.1% Imidacloprid and 9.1% Imidacloprid + 0.46% Pyriproxyfen Spot-on Products	49469206	Sergeant's Pet Care Products	OWN	
Toxicology Data Requirements					
870.1100	Acute Oral Toxicity Up and Down Procedure with CVSG 003	49510307	Sergeant's Pet Care Products	OWN	
870.1200	Acute Dermal Toxicity Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On in Rats	45096905	Bayer Animal Health	PAY	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for the Following Sergeant's Products: Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats	49510306	Sergeant's Pet Care Products	OWN	
870.2400	Primary Eye Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On in Rats	45096907	Bayer Animal Health	PAY	
870.2500	Primary Dermal Irritation Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On in Rats	45096908	Bayer Animal Health	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 23, 2014	

e-Submission



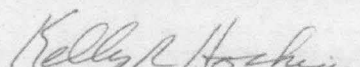
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DATA MATRIX

Date: December 23, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 2 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal Sensitization Study with Imidacloprid (9.1%)/Pyriproxyfen (0.9%) Spot On in Rats	45096909	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Seven Week Old Puppies	45097101	Bayer Animal Health	PAY	
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Adult Dogs	45097102	Bayer Animal Health	PAY	
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay t 7391) Spot-on: Lab Project Number: 74580: TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Dogs: Lab Project Number: 74590: TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Animal Health	OLD	
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003: 74730: 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Animal Health	OLD	
870.7200	Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.	44179801	Bayer Animal Health	OLD	
Product Performance Test Guidelines					
810.3300	Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs	43679609	Bayer Animal Health	OLD	
810.3300	Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs	43679610	Bayer Animal Health	OLD	
810.3300	A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Animal Health	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 23, 2014	



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Page 1 of 3

Applicant's/Registrant's Name & Address

Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710

Product:

Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs

Ingredients: Imidacloprid, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Sergeant's Pet Care Products	OWN	
			Bayer Animal Health	PAY	
			Sergeant's Pet Care Products	OWN	
			Bayer Animal Health	PAY	
			Bayer Animal Health	PAY	
			Bayer Animal Health	PAY	

Signature

Name and Title

Kelly R. Hoskins, Director of Regulatory Affairs

Date

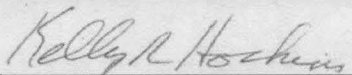
December 23, 2014

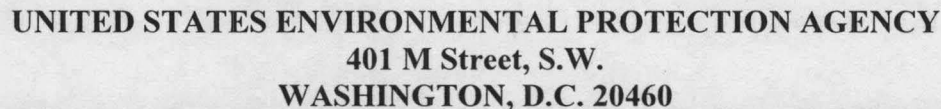


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 23, 2014		EPA Reg No./File Symbol: 2517-NEW		Page 2 of 3	
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710		Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs			
Ingredients: Imidacloprid, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer Animal Health	PAY	
			Bayer Animal Health	PAY	
			Bayer Animal Health	PAY	
			Bayer Animal Health	OLD	
			Bayer Animal Health	OLD	
			Bayer Animal Health	OLD	
			Bayer Animal Health	OLD	
			Bayer Animal Health	OLD	
			Bayer Animal Health	OLD	
			Bayer Animal Health	PAY	
Signature 		Name and Title Kelly R. Hoskins, Director of Regulatory Affairs		Date December 23, 2014	



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Date: December 23, 2014	EPA Reg No./File Symbol: 2517-NEW	Page 3 of 3
Applicant's/Registrant's Name & Address Sergeant's Pet Care Products, Inc., 10077 South 134th Street, Omaha, NE 68138-3710	Product: Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs	
Ingredients: Imidacloprid, Pyriproxyfen		

Signature 	Name and Title Kelly R. Hoskins, Director of Regulatory Affairs	Date December 23, 2014
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Sergeant's® Master Label

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FRONT PANEL

Dogs Squeeze On Imidacloprid + Pyriproxyfen

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text on front, back or side label panels]

Sergeant's® Imidacloprid + Pyriproxyfen Squeeze On for Dogs

[ABNs]

[SENTRY Vet for Dogs Imidacloprid + Pyriproxyfen]
[SENTRY Vet Advanced Flea for Dogs]
[SENTRY Vet FleaGuard for Dogs]
[SENTRY Vet Vantage for Dogs]
[SENTRY Vet Vantage II for Dogs]
[SENTRY Vet Flea Vantage for Dogs]
[SENTRY Advanced for Dogs Imidacloprid + Pyriproxyfen]
[SENTRY Advanced FleaGuard for Dogs]
[SENTRY Advanced Vantage for Dogs]
[SENTRY Advanced Vantage II for Dogs]
[SENTRY Advanced Flea Vantage for Dogs]
[SENTRY Advanced VetSpot for Dogs]
[PetArmor II for Dogs]
[PetArmor Vantage for Dogs]
[PetArmor Vantage II for Dogs]
[PetArmor Advant for Dogs]
[PetArmor FleaGuard for Dogs]
[PetArmor Advanced for Dogs]
[PetArmor Vet II for Dogs]
[PetArmor Flea Vantage for Dogs]
[PetArmor Adv Flea for Dogs]
[PetArmor Adv.Flea for Dogs]
[PetArmor AdvVet for Dogs]
[SENTRY 3-Way Advanced]
[Pet Armor 3-Way Advanced]
[SENTRY 3 Way Advanced]
[Pet Armor 3 Way Advanced]

For use ONLY on dogs [[&][and] puppies] [weighing] [3 [-][to] 10 lbs.] [11 [-][to] 20 lbs.] [21 [-][to] 55 lbs.] [[more than][over][>] 55 lbs.] and [over 7 weeks [old][of age]][7 weeks [of age] or older] {OR}

ONLY for dogs [[&][and] puppies]] [over 7 weeks [old][of age]][7 weeks [of age] or older] and [weighing] [3 [-][to] 10 lbs.] [11 [-][to] 20 lbs.] [21 [-][to] 55 lbs.] [[more than][over][>] 55 lbs.]

[1.5cm x 1.5cm on final or as indicated]



[Apply to [dogs and] [puppies] over 7 weeks old]
[Apply to [dogs and] [puppies] 7 weeks or older]

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[Active Ingredient Reference Statements]

[Contains imidacloprid and pyriproxyfen, [the] [same] active ingredients used in [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].*]

[Contains imidacloprid and pyriproxyfen, [the] [same] active ingredients used in [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].*]

[Contains imidacloprid and pyriproxyfen, [the] [same] active ingredients used in [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].*]

[Contains imidacloprid and pyriproxyfen, [the] [same] active ingredients used in [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].*]

[Compare to the active ingredients in [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].*]

[Compare to the active ingredients in [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].*]

[Compare to the active ingredients in [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].*]

[Compare to the active ingredients in [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].*]

[Contains [the] [same] active ingredients used in [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].*]

[Contains [the] [same] active ingredients used in [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].*]

[Contains [the] [same] active ingredients used in [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].*]

[Contains [the] [same] active ingredients used in [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].*]

[Compare to [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs], contains the same active ingredients.*]

[Compare to [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs], contains the same active ingredients.*]

[Compare to [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs], contains the same active ingredients.*]

[Compare to [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs], contains the same active ingredients.*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, [the] [same] [an] active ingredients used in [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, [the] [same] [an] active ingredients used in [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, [the] [same] [an] active ingredients used in [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, [the] [same] [an] active ingredients used in [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].*]

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[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, compared to [the] [same] active ingredients used in [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, compared to [the] [same] active ingredients used in [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, compared to [the] [same] active ingredients used in [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].*]

[[Brand Name] [products] [This product] contain(s) imidacloprid and pyriproxyfen, compared to [the] [same] active ingredients used in [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs].]

[[*][Brand Name][This product] is not manufactured or distributed by [Bayer Healthcare LLC] [Company name], the makers of [Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs].]

[*[Advantage[®] II Small Dog] [Advantage[®] Plus 10 for Dogs] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage[®] II Medium Dog] [Advantage[®] Plus 20 for Dogs] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage[®] II Large Dog] [Advantage[®] Plus 55 for Dogs] is a registered trademark of Bayer Healthcare LLC.]

[*[Advantage[®] II Extra Large Dog] [Advantage[®] Plus 100 for Dogs] is a registered trademark of Bayer Healthcare LLC.]

[Fleas]

[[Brand Name][This product] is indicated for the treatment and prevention of fleas on dogs [over 7 weeks [old][of age]][7 weeks [of age] or older]]

[[Brand Name] Prevents further flea infestation for [up to] [[four][4] weeks][[1][one][a] month]]

[[Once per month][Monthly] topical flea treatment for dogs [over 7 weeks [old][of age]][7 weeks [of age] or older]]

[Prevents and treats flea[s] [infestations]]

[Kills flea larvae in treated dog's surroundings]

[Controls existing infestations by killing adult fleas]

[Kills adult fleas before they lay eggs, preventing reinfestation]

[Use of [Brand Name][this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Monthly treatment with [Brand Name][this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] [flea allergy dermatitis] [FAD]]

[Protects against [irritating] flea bites]

[Controls problems associated with fleas]

[Use year-round for control of fleas]

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[Protects against the [infestation][reinfestation] of the home by fleas on treated dogs]
[Controls fleas, which can serve as an intermediate tapeworm host]
[Stops and prevents infestation of listed pests for 4 weeks]
[Prevents [further] flea infestation for [[four][4] weeks][1 month] with [just] one
[treatment][application]
[Brand Name] Prevents flea infestation for [four][4] weeks][1 month]
[Kills fleas within 12 hours [of application] on dogs]
[Kills reinfesting fleas within 2 hours]
[Kills [adult] fleas before they lay eggs]
[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin
disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of
fleas on dogs.]
[Kills flea larvae in dog's surroundings following contact with treated dog]
[Apply monthly [for optimal flea control][to control and prevent fleas]]
[Kills fleas]
[Complete Flea [Control] [Protection]]
[Optimal Flea [Control] [Protection]]
[Advanced Flea [Control] [Protection]]
[Kills fleas in 12 hours, continues to kill for 4 weeks]
[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]
[Kills fleas, which may be a source of flea allergy dermatitis [, within][in] 12 hours]
[Flea protection]
[Active against fleas]
[Kills fleas on [puppies] [and] [dogs]]
[[Brand Name] Offers protection against fleas]
[Flea control for puppies and dogs [over 7 weeks [old]][of age]][7 weeks [of age] or older]]
[Kills fleas within [12] hours [of application] on dogs [and prevents infestations for [up to]
[[4][four] weeks][[1][one][a] month]]

[IGR]

[Prevents flea eggs from hatching]
[Prevents flea eggs from developing into [biting] adult fleas]
[Prevents the development of flea [eggs] [larvae] into biting adult fleas]
[Kills flea adults, larvae, and eggs [, providing three-way protection]]
[[Controls][Kills] flea eggs]
[[Brand Name][This product] Contains [Pyriproxyfen][PPF]] [an insect growth regulator (IGR)]
to kill flea eggs [and protect against reinfestation]]
[Kills flea eggs, larvae, and [adult] fleas in the dog's surroundings following contact with a
treated dog]
[[Targets][Controls] all stages of flea lifecycle]
[[Brand Name][This product] is a flea ovicide, larvicide, and adulticide]
[Kills flea eggs]
[Provides multi-stage flea control]
[Kills fleas, flea eggs, and flea larvae]
[Kills [fleas] [flea eggs] [flea larvae]]
[Breaks the flea life cycle]
[Kills flea eggs and flea larvae for up to 4 weeks]
[Prevents all stages of the flea life cycle from developing]

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[[Brand Name][This product] inhibits the immature flea life stages from developing, preventing them from becoming [biting] adult[s] [fleas]]

[Controls existing flea eggs and fleas and [stops][prevents] future infestations]

[All Others]

[Brand Name] contains [an][the] [insect growth regulator] [IGR] [, Pyriproxyfen] [, in addition to imidacloprid]

[Begins working through contact]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight] [and][or] [rain]]

[Remains effective even after [bathing] [,][and] [shampooing] [,][and] [water immersion] [,][and] [exposure to [sunlight] [and][or] [rain]]]

[Remains effective even after the dog swims]

[[Sergeant's] Caring For Your Pets Since 1868]

[For Dogs]

[For use ONLY on dogs]

[Specially Formulated for Dogs and Puppies [Over 7 Weeks [Old]][of Age]][7 Weeks [of Age] or Older]]

[Dogs and Puppies [over 7 weeks [old]][of age]][7 weeks [of age] or older]]

[Can be used on puppies [over 7 weeks [old]][of age]][7 weeks [of age] or older]]

[The Only Flea Protection You Need For Your Dog[s]!]

[Original Vet Strength]

[Fast Acting] [Long Lasting]

[Convenient]

[Easy application]

[Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[Best if used year round!]

[X Applications] [4 Week Supply] [1 Month Supply]

[One Application] [8 Week Supply] [2 Month Supply]

[Two Applications] [12 Week Supply] [3 Month Supply]

[Three Applications] [16 Week Supply] [4 Month Supply]

[Four Applications] [20 Week Supply] [5 Month Supply]

[Five Applications] [24 Week Supply] [6 Month Supply]

[Six Applications] [48 Week Supply] [12 Month Supply]

[9 Applications] [52 Week Supply] [24 Month Supply]

[12 Applications] [104 Week Supply]

[24 Applications]

[[for] Small Dog[s] [10 lbs. and under] [3 [to][–] 10 lbs.]]

[[for] Medium Dog[s] [11 [to][–] 20 lbs.]]

[[for] Large Dog[s] [21[to][–] 55 lbs.]]

[[for] Extra Large Dog[s] [Over 55 lbs.]]

[Direct to skin [tube][vial][applicator][pipette]]

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[Easy to Use] [tube][vial][applicator][pipette]
[Clean cut [open] [tube][vial][applicator][pipette]]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette][!]]

ACTIVE INGREDIENTS:

Imidacloprid.....9.10%
Pyriproxyfen0.46%

OTHER INGREDIENTS:90.44%

[TOTAL]100.00%]

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][or][Side][Label[s][Panel[s]] for Additional Precautionary Statements]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[0.014 fl oz (0.4 mL) [tubes][vials][applicators][pipettes]]

[0.034 fl oz (1.0 mL) [tubes][vials][applicators][pipettes]]

[0.085 fl oz (2.5 mL) [tubes][vials][applicators][pipettes]]

[0.135 fl oz (4.0 mL) [tubes][vials][applicators][pipettes]]

{END – FRONT PANEL}

BACK PANEL/SIDE PANEL OR INSERT

**Dogs Squeeze On
Imidacloprid + Pyriproxyfen**

[The active ingredients in [Brand name][this product] are [imidacloprid and pyriproxyfen,] formulated for fast acting [and long lasting] control of fleas [, flea eggs, and flea larvae] on dogs.] [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][[1][one] month][30 days].]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

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FIRST AID	
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything to an unconscious person.
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on Skin	<ul style="list-style-type: none">• Wash with plenty of soap and water/
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 7 weeks of age or less than [3] [11] [21] [55] lbs. Use entire contents of [tube][vial][applicator][pipette] on each dog. [Do not split one [tube][vial][applicator][pipette] between dogs.] Do not use multiple [tube][vial][applicator][pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5 cm x 1.5 cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. Contact your veterinarian if applied to a cat or ingested by a cat.

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{OUTER PACKAGING}

How to Open: Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to Apply: Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [30 days][4 weeks][month].

{For cartons containing 0.4 mL (0.014 fl oz) applicator tubes}

Only For Dogs Weighing 3 [-][to] 10 lbs. [Do not apply to dogs weighing less than 3 lbs.

including small dogs and puppies, only 7 weeks or older]] Apply one

[tube][vial][applicator][pipette] 0.4 mL (0.014 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 1.0 mL (0.034 fl oz) applicator tube}

Only For Dogs Weighing 11 [-][to] 20 lbs. [Do not apply to dogs weighing less than 11 lbs.]

Apply one [tube][vial][applicator][pipette] 1.0 mL (0.034 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 2.5 mL (0.085 fl oz) applicator tube}

Only For Dogs Weighing 21 [-][to] 55 lbs. [Do not apply to dogs weighing less than 21 lbs.]

Apply one [tube][vial][applicator][pipette] 2.5 mL (0.085 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

{For cartons containing 4.0 mL (0.135 fl oz) applicator tube}

Only For Dogs Weighing 55 lbs. or greater. [Do not apply to dogs weighing less than 55

lbs.] [Do not use two [tube][vial][applicator][pipette]s on dogs greater than 55 lbs.] Apply one [tube][vial][applicator][pipette] 4.0 mL (0.135 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on][to] the dog's back between the shoulder blades][as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.]

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FREQUENCY OF APPLICATION

[Use [Brand Name][this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name][This product] kills fleas within 12 hours of application and [lasts][protects] [for [up to] [[four][4] weeks][30 days][one month].] [[Brand Name][This product] kills reinfesting fleas within [2 hours][two hours] and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].] [[Brand Name][This product] [targets all flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].] [[Brand Name][This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.] [If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly.] [Apply monthly for optimal flea control.] [[Brand Name][This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.] [Do not reapply for [4 weeks][30 days].]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove [tube][vial][applicator][pipette] from the pack until ready to use. Store only in original container in a cool [(below 77°F)[/][25°C]], dry area inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710
{END - BACK/SIDE PANEL}

EPA Reg. No. 2517-NEW
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

Sergeant's[®] Master Label

23 December 2014

Version 14.1

EPA Reg. No. 2517-NEW

Information in [] is optional.

Information in { } is note to reviewer.

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{START - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE}

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea protection where it needs to be.]

[Application Instructions][Directions for Use]

How to Open:

1. Remove product [tube[s]][vial[s]][applicator[s]][pipette[s]] from the package.
2. [Separate one [tube][vial][applicator][pipette] from the others.] Hold the [tube][vial][applicator][pipette] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube][vial][applicator][pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube][vial][applicator][pipette] firmly to apply all of the solution [on] [to] the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette] between dogs][and use the ENTIRE [tube][vial][applicator][pipette] contents]

[Brand Name][This product]

[Monthly reminder card]

[1][2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

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Information in { } is note to reviewer.

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[33% More Free]

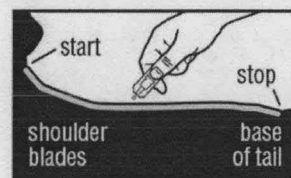
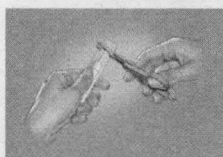
[Bonus Size]

[Buy 3 get 1 free]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Each optional graphic below may or may not appear anywhere on the finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	



DO NOT USE
ON CATS



MADE IN THE
USA



MADE IN THE
USA
WITH GLOBAL MATERIALS



Sergeant's[®] Master Label

23 December 2014

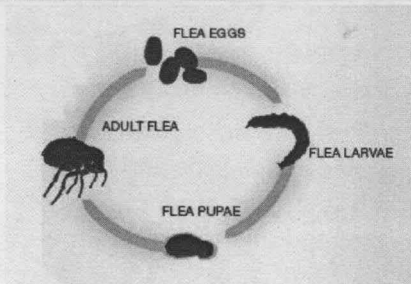
Version 14.1

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[Flea life cycle diagram] [Flea Life Cycle]

{END – OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

Dogs Squeeze On
Imidacloprid + Pyriproxyfen

{Front Label}

[**Brand Name** (for dogs)]
[X-Y] lbs. ≥7 wks
Imidacloprid 9.10%, Pyriproxyfen 0.46%
0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz
(or) 0.135 fl oz {label code}



{Back Label}

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions
before using. Use scissors to open.
EPA REG. No. 2517-XXX {label code}

{EPA REG No may be on either the front or back label}

{END – TUBE/VIAL LABEL}